EXHIBIT 53

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR DISEASE CONTROL AND PREVENTION
National Center for Emerging and Zoonotic Infectious Diseases
Division of Healthcare Quality Promotion

Healthcare Infection Control Practices Advisory Committee
November 5-6, 2015
Atlanta, Georgia

Record of the Proceedings

Table of Contents

Meeting Agenda 3
List of Participants 4
Executive Summary 7
Welcome and Introductions 8
CDC Updates: Division of Healthcare Quality Promotion 9
Healthcare Antimicrobial Stewardship 12
Nontuberculous Mycobacterium Infections Associated with Heater-Cooler Devices 24
Update: Research Framework for Environmental Infection Control: Environmental Surfaces 32
Considerations for Evidence-Based Evaluations for New and Evolving Proprietary Products for Infection Control 34
Using Data for Prevention: Targeted Assessment for Prevention (TAP) 40
Update on HICPAC Workgroup for Endoscope Reprocessing 47
Public Comment 49
Recognition of Retiring Members 50
Liaison / *Ex Officio* Reports 51
Adjourn 57
Control of Antimicrobial Resistance Across Healthcare Settings 57
Sepsis Surveillance Definition Work Update 65
Ensuring Training and Competency of Healthcare Personnel in Infection Control 69
Summary and Work Plan 71
Public Comment 73
Adjourn 73
Certification 74
Attachment #1: Acronyms Used in this Document 75
Attachment #2: Liaison and Ex-Officio Reports 78
Clinical Practice Guidelines for Antimicrobial Prophylaxis in Surgery 109
Guidelines for Developing an Institutional Program to Enhance Antimicrobial Stewardship 110
Guidelines for the Prevention of Antimicrobial Resistance in Hospitals 110

Meeting Agenda
Healthcare Infection Control Practices Advisory Committee

November 5-6, 2015
Centers for Disease Control and Prevention
Tom Harkin Global Communications Center (Building 19, Auditorium 3)
1600 Clifton Road NE, Atlanta, GA

Thursday, November 5, 2015

9:00	Welcome and Introductions	Information	Dan Diekema (HICPAC Chair) Jeff Hageman (HICPAC DFO)
9:15	CDC Updates: Division of Healthcare Quality Promotion (DHQP)	Information	Denise Cardo (DHQP,CDC)
9:30	Healthcare Antimicrobial Stewardship	Information Discussion	Arjun Srinivasan (DHQP, CDC) Lauri Hicks (DHQP, CDC)
11:00	Nontuberculous Mycobacterium Infections Associated with Heater-Cooler Devices	Information Discussion	Joe Perz (DHQP, CDC) Michael Bell (DHQP, CDC)
1:30	Update: Research Framework for Environmental Infection Control: Environmental Surfaces	Information	Sujan Reddy (Emory University)
1:45	Approach to Evidence-Based Evaluations for New and Evolving Proprietary Products for Infection Control	Information Discussion	Erin Stone (DHQP, CDC)
2:30	Using Data for Prevention: Targeted Assessment for Prevention (TAP)	Information Discussion	Carolyn Gould (DHQP)
3:45	Update on HICPAC Reprocessing Workgroup	Information Discussion	Jeff Hageman (HICPAC DFO)
4:15	Public Comment		
4:30	Liaison/*ex officio* reports		
5:00	**Adjourn**		

Friday, November 6, 2015

9:00	Welcome and Roll Call	Information	Dan Diekema (HICPAC Chair) Jeff Hageman (HICPAC DFO)
9:15	Control of Antimicrobial Resistance Across Healthcare Settings	Information Discussion	John Jernigan (DHQP, CDC)
10:15	Sepsis Surveillance Definition Update	Information	Anthony Fiore (DHQP, CDC)
10:45	Ensuring Training and Competency of Healthcare Personnel Infection Control	Information Discussion	Michael Bell (DHQP, CDC)
11:15	Public Comment		
11:30	Summary and Work Plan		
12:00	**Adjourn**		

List of Participants

November 5, 2015

HICPAC Members
Dr. Daniel Diekema, Chair
Dr. Hilary Babcock
Ms. Vickie Brown
Dr. Sheri Chernetsky-Tejedor
Dr. W. Charles Huskins
Dr. Susan Huang
Ms. Lynn Janssen
Dr. Lisa Maragakis
Dr. Jan Patterson
Ms. Gina Pugliese
Dr. Tom Talbot
Dr. Deborah Yokoe

***EX OFFICIO* MEMBERS**
Ms. Elizabeth Claverie-Williams, Food and Drug Administration
Dr. David Henderson, National Institutes of Health
Dr. Gary Roselle, Veteran's Administration
Dr. Daniel Schwartz, Centers for Medicare and Medicaid Services
Ms. Judy Trawick, Health Resources and Service Administration

LIAISON REPRESENTATIVES
Mr. Michael McElroy (America's Essential Hospitals)
Dr. Mark Russi (American College of Occupational and Environmental Medicine (ACOEM))
Ms. Amber Wood (Association of periOperative Registered Nursed (AORN))
Ms. Michael Anne Preas (Association of Professionals of Infection Control and Epidemiology (APIC))
Dr. Emily Lutterloh (Association of State and Territorial Health Officials (ASTHO))
Ms. Marion Kainer (Council of State and Territorial Epidemiologists (CSTE))
Ms. Lisa McGiffert (Consumers Union)
Ms. Linda Spaulding (DNV Global Healthcare)
Dr. Stephen Weber (Infectious Diseases Society of America (IDSA))
Dr. Sarah Matthews (National Association of County and City Health Officials (NACCHO))
Ms. Toju Ogunremi (Public Health Agency of Canada (PHAC))
Dr. Michael Howell (Society for Critical Care Medicine (SCCM))
Dr. David Banach (Society for Healthcare Epidemiology of America (SHEA)
Dr. Robert Sawyer (Surgical Infection Society (SIS))

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Ms. Denise Albina, CDC/ DHQP
Ms. Sonya Arundar, CDC/ DHQP
Dr. Michael Bell, CDC/ DHQP
Dr. Denise Cardo, CDC/DHQP
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Dr. Matthew Crist, CDC/ DHQP
Dr. Bryan Christiansen, CDC/ DHQP
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Dr. Scott Fridkin, CDC/DHQP
Ms. Nancy Gallagher, CDC/DHQP
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Dr. Kathleen Irwin, CDC/DHQP
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Dr. Meghan Lyman, CDC/ DHQP
Dr. Cliff MacDonald, CDC/ DHQP

Ms. Dyann Matson Koffman, CDC/OSQ/OADS
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Dr. Shelley Magill, CDC/ DHQP
Ms. Kerri Moran, CDC/DHQP
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Ms. Amibola Ogundimu, CDC/DHQP
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Dr. Joe Perz, CDC/DHQP
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Ms. Kathy Sieber, CDC/ DHQP
Ms. Erin Stone, CDC/ DHQP
Dr. Nicola Thompson, CDC/ DHQP
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Ms. Wendy Vance, CDC/DHQP
Ms. Ellen Wan, CDC/DHQP
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Dr. Cindy Weinbaum, CDC/ DHQP
Ms. Sarah Yi, CDC/ DHQP

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Ms. Kay Argroves, American Association of Nurse Anesthetists
Mr. Nick Austerman, Bard Medical
Ms. Nicole Bryan, CSTE
Dr. Russ Castioni, 3M
Ms. Kendra Cox, Cambridge Communications, Training, and Assessments
Ms. Pamela Falk, Northside Hospital
Mr. Hudson Garrett, PDI
Ms. Maryellen Guinan, America's Essential Hospitals
Ms. Amna Handley, GA Pacific
Ms. Linda Homan, Ecolab
Ms. Eve Humphries, Society of Healthcare Epidemiologist of America
Dr. Jesse Jacob, Emory University
Mr. Robert Jones, Goldshield/ Energy and Environmental
Ms. Jane Kirk, Gojo Industries
Ms. Beth Morrow, Northside Hospital
Ms. Renee Odehnal, Ethicon
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Ms. Maria Rodriguez, Xenex
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Ms. Lisa Tomlinson, APIC
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November 6, 2015

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Ms. Tanya Cassingham, CDC/ DHQP
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Dr. Tony Fiore, CDC/ DHQP
Dr. Scott Fridkin, CDC/DHQP
Ms. Nancy Gallagher, CDC/ DHQP
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Mr. Emmanuel Maurice, CDC/ DHQP
Ms. Kelly McCormick, CDC/ DHQP
Ms. Kerri Moran, CDC/DHQP
Ms. Heather Moulton-Meissner, CDC/ DHQP
Mr. Justin O'Hagan, CDC/ DHQP
Ms. Amibola Ogundima, CDC/ DHQP
Ms. Danielle Palms, CDC/ DHQP
Dr. Priti Patel, CDC/ DHQP
Dr. Kiran Perkins, CDC/ DHQP
Dr. Joe Perz, CDC/DHQP
Ms. Jan Ratterree, CDC/ DHQP
Dr. Sujan Reddy, CDC/ DHQP
Dr. Issac See, CDC/ DHQP
Ms. Alicia Shugart, CDC/ DHQP
Ms. Erin Stone, CDC/ DHQP
Ms. Abbigail Tumpey, CDC/ DHQP
Ms. Wendy Vance, CDC/ DHQP
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Ms. Sarah Yi, CDC/ DHQP

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Ms. Lisa Tomlinson, APIC

Executive Summary

The US Department of Health and Human Services (HHS) and the Centers for Disease Control and Prevention (CDC) National Center for Emerging and Zoonotic Infectious Diseases (NCEZID) Division of Healthcare Quality Promotion (DHQP) convened a meeting of the Healthcare Infection Control Practices Advisory Committee (HICPAC) on November 5-6, 2015 in Atlanta, Georgia. The Designated Federal Official (DFO) and Chair confirmed the presence of a quorum of HICPAC voting and *ex officio* members on both days of the meeting.

The meeting was called to order at 9:22 am. on November 5, 2015. Dr. Denise Cardo provided updates and future directions from DHQP. Drs. Arjun Srinivasan and Lauri Hicks updated HICPAC on DHQP's efforts in healthcare antimicrobial stewardship. HICPAC heard information on nontuberculous mycobacterium infections associated with heater-cooler devices from Drs. Joe Perz and Michael Bell and then held discussions. Dr. Sujan Reddy updated HICPAC on the research framework for environmental infection control pertaining to environmental surfaces. Ms. Erin Stone presented, and HICPAC reviewed and discussed, an approach to evidence-based evaluations for new and evolving proprietary products for infection control. Dr. Carolyn Gould presented on using data for prevention using the Targeted Assessment for Prevention (TAP). HICPAC received an update on the HICPAC Reprocessing Workgroup. There was a public comment period, and HICPAC recognized retiring members Dr. Susan Huang and Ms. Gina Pugliese. HICPAC liaison groups provided written and verbal updates. HICPAC stood adjourned from 5:01 pm on November 5 until 9:07 am on November 6.

On Friday, November 6, 2015, Dr. John Jernigan presented to HICPAC regarding control of antimicrobial resistance across healthcare settings. Dr. Anthony Fiore presented on DHQP's work regarding a sepsis surveillance definition. Dr. Michael Bell led a discussion on ensuring training and competency of healthcare personnel in infection control. HICPAC discussed a future work plan and held a public comment period.

HICPAC stood in recess at 11:25 am on November 6, 2015. The next HICPAC meeting will be held in Atlanta, Georgia on March 31-April 1, 2016.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR DISEASE CONTROL AND PREVENTION
National Center for Emerging and Zoonotic Diseases
Division of Healthcare Quality Promotion

Healthcare Infection Control Practices Advisory Committee (HICPAC)

November 5-6, 2015
Atlanta, Georgia

DRAFT Minutes of the Meeting

The United States Department of Health and Human Services (HHS) and the Centers for Disease Control and Prevention (CDC) National Center for Emerging and Zoonotic Infectious Diseases (NCEZID) Division of Healthcare Quality Promotion (DHQP) convened a meeting of the Healthcare Infection Control Practices Advisory Committee (HICPAC) on July 16-17, 2015 at the Tom Harkin Global Communications Center at the Centers for Disease Control and Prevention, 1600 Clifton Road NE, Atlanta, Georgia.

Thursday, November 5, 2015

Welcome and Introductions

Jeff Hageman
Division of Healthcare Quality and Promotion
National Center for Emerging and Zoonotic Infectious Diseases
Centers for Disease Control and Prevention
Designated Federal Official, Healthcare Infection Control Practices Advisory Committee

Mr. Jeff Hageman called the meeting to order at 9:22 am. He welcomed HICPAC members, *ex officio* members, and liaison representatives, and conducted a roll call. A quorum was present. HICPAC members disclosed the following conflicts of interest:

- Dr. Daniel Diekema has received research funding from bioMérieux.
- Ms. Jan Patterson's spouse has been a consultant for Astellus Pharma, Endo International, and Viamet.
- Ms. Lynn Janssen's spouse works for Dynavax Technologies, which immunologic products, including vaccines.
- Dr. W. Charles Huskins served as an advisory board member to Genentech.
- Dr. Tom Talbot's spouse has received research funding from MedImmune, Sanofi Pasteur, and Gilead Sciences, Inc, and is on the advisory committee for Novartis.
- Dr. Lisa Maragakis receives research funding from Clorox and Versa.
- Dr. Susan Huang is conducting clinical trials and research studies in which participating hospitals and nursing homes receive contributed product from Sage Products, Mölnlycke Healthcare, 3M, and Clorox.

CDC Updates: Division of Healthcare Quality Promotion

Denise Cardo, MD
Director, Division of Healthcare Quality Promotion
National Center for Emerging and Zoonotic Infectious Diseases
Centers for Disease Control and Prevention

Dr. Cardo provided an update on DHQP's direction and areas where HICPAC and its liaisons can provide advice and support. Over the past several years progress has been made in preventing healthcare-associated infections through the implementation CDC and HICPAC recommendations. However, more work needs to be done to increase adherence and implementation of the recommendations that are known to be effective.

Dr. Cardo also provided an overview of DHQP's data sources that provide information to target prevention and response efforts including information from outbreaks reported to CDC, the National Healthcare Safety Network (NHSN) and the Emerging Infections Program (EIP). These sources complement each other and add to understanding regarding what is happening, even to the unit or pathogen level, and to better promote prevention and work with partners.

Dr. Cardo also emphasized that DHQP's partnerships are critical for improving patient safety nationally. Over the years, DHQP has expanded not only the partners with which it works, but also the partners it supports through funding. The HICPAC liaisons represent many of DHQP's partner organizations that range from professional societies, healthcare organizations, accreditation organizations, public health associations, federal agencies involved in healthcare issues, and consumers. HICPAC liaisons are encouraged to share the activities that their organizations are undertaking for promoting healthcare-associated infection (HAI) issues, addressing barriers, and facilitating implementation. HICPAC liaison input during HICPAC meetings is critical not only for science, but also for working faster and better to protect patients.

At the same time, the division is expanding its role in supporting research. In addition to intramural research, the division's role in extramural research is expanding through the Safety and Healthcare Epidemiology Prevention Research Development (SHEPheRD) and the Prevention Epicenters, as well as other mechanisms. Two of the main goals of DHQP are to prevent infections and improve patient care. Dr. Cardo outlined several of DHQP's research topics include:

- New interventions for better detection and prevention of infections and antibiotic resistance (AR): The division's isolate bank has been made available to look for new diagnostics or to test new treatments. The division is also considering how its data and expertise can contribute to the development of new vaccines for HAIs.
- The role of the environment in transmission of HAIs: The division is funding extramural research and conducting intramural research in this area.
- Microbiome: DHQP is partnering with several groups to better understand the microbiome and how it may help with the prevention of infections and resistance.
- Improving stewardship across healthcare not just by settings, but by funding research to determine the best interventions and ways to look at data across healthcare.

- Utilizing modeling to understand the spread of pathogens: the division has embraced modeling, especially when randomized controlled trials (RCTs) cannot be conducted or when the field cannot wait for their results.
- Advanced microbiology tools, such as sequencing, work with modeling to understand dynamics, to better understand infections and resistance, and to focus prevention.

Dr. Cardo also highlighted several areas where DHQP has been expanding efforts including:

Medical Devices
Medical devices have been part of the division for some time, but as devices advance, the field of infection prevention and control is behind. Devices are becoming more complex and sometimes less invasive, but they rarely consider infection prevention and control. The field should not only conduct outbreak investigations, but also should be prepared for the future with strategies to participate in the development of the devices that do not have unintended adverse consequences to patients.

Environmental Infection Control
This area is sometimes related to medical devices, but non-device outbreaks can occur. For instance, Carbapenem-resistant *Enterobacteriaceae* (CRE) outbreaks have been linked to sinks or to biofilm found in plumbing. The field must move beyond patient-to-patient transmission and use all of the different available tools to create interventions.

Post-Acute Healthcare Settings
DHQP is more present in post-acute healthcare settings such as ambulatory centers and long-term care facilities. This requires different roles and levels of involvement, but the division is helping the field move forward.

Stewardship
Stewardship is a priority for HHS, and CDC is the lead agency for these federal activities with DHQP leading CDC's activities in this area. DHQP also serves as a connection for its federal partners and its partners in healthcare. It is time to consider stewardship with new paradigms and new expectations for making a difference. A new Office of Antibiotic Stewardship has assembled stewardship activities across the continuum of healthcare together within DHQP.

Sepsis
DHQP has become more involved in better diagnosing sepsis, recognizing early sepsis, and including sepsis as part of stewardship.

Preparedness and Response
This area is focused on Ebola, Middle East Respiratory Syndrome Coronavirus (MERS-CoV), and other emerging infections. DHQP supports state and local health departments as well as hospitals to create better connections.

This HICPAC meeting agenda addresses the above roles and activities. CDC counts on advice from HICPAC and the liaison representatives not only in creating recommendations, but also in setting directions for moving forward and for helping move the field forward. HICPAC also helps with implementation in the field to make positive changes.

Discussion Points

HICPAC commented on a recently-published study in the *New England Journal of Medicine* (*NEJM*) which was a randomized trial of outcomes associated with the placement of central venous lines in different locations. The study examined line insertion-related complications, thrombosis, and bloodstream infection. In some cases, the data showed competing risks. Depending upon where the line was inserted, one risk was higher than the other. This concept is important in thinking about risks associated with medical devices and from the standpoint of the bedside. Providers deal with initiatives related to central line-associated bloodstream infection (CLABSI), venous thromboembolism (VTE), and other concerns. Perhaps these initiatives can be integrated in a better way so that providers think more broadly about the risks associated with a central line rather than just about CLABSI prevention.

Dr. Cardo replied that this idea is critical. The focus should be on the patient and on the risks and benefits of everything that providers do, not only in the prevention of infections, but also in the prevention of other adverse consequences. Also, the unintended consequences of what CDC recommends should be considered. The initial approach to infection prevention and control utilized checklists, and increasing adherence made a difference. Now that work should take place in a manner that focuses on the patient. This focus should be applied in all categories, such as sepsis. Early recognition of sepsis can include blood cultures and reassessment of antibiotics. CDC's recommendations should be part of the process of care so that it will be easier for clinicians to do what is needed for a specific patient. Health systems are moving toward performing checklists by patient rather than device. This change is challenging, but without moving in that direction it will be difficult to make a difference. Even in stewardship, antibiotics should be considered based not only on a condition, but also on which antibiotic option should be administered first. The goal should not be decrease for the sake of decrease, but should take into account which antibiotics will cause the most harm to the patient. HICPAC's feedback will be necessary in making this change, as the guidelines are specific and should be put into a context of care.

HICPAC recognized that these issues are all important. The public reporting of events has made a positive impact in institutions to build interest and investment in programs. One element of the reporting that should be addressed is inadequate risk adjustment of reported data. Hospitals that are invested in reducing these events are struggling because they have momentum but are still penalized. In the success with reporting, this issue should not be forgotten. There is increasing frustration with events that are unique and concern about whether institutions have equivalent settings. There is exciting work occurring regarding risk adjustment of the measures, getting accurate data that can be used, and providing information about what is preventable.

Dr. Cardo agreed and said that this issue is ongoing. There was a past HICPAC working group that helped with definitions and metrics. It may be time to create a similar group. In some hospitals, patients are not getting cultures so that infections will not be reported. This practice is not good. It is important to consider the situation in its entirety, as there have been unintended consequences from CDC being assertive.

Regarding the medical devices issue, especially relating to scopes that are reprocessed and reused, Consumer's Union observed that the issue seems to center on cleaning. CDC should speak up about this issue and state that cleaning processes should be shown to work before a device is cleared to be on the market. The duodenoscope issues showed that after the fact when the manufacturers came in for reprocessing, the process did not clean out the bacteria.

Medical device laws will be reviewed in 2017, so it is a good time for CDC to speak up on the infection prevention side to ensure that they are safe.

Dr. Cardo said that one of the approaches is not only to provide strategies for personnel to clean better, but also to establish requirements for new devices. It is important to ensure manufacturers are responsible for guaranteeing that devices are compatible with cleaning and disinfection products.

FDA clarified that because it is a regulatory agency, details of the review process cannot be discussed. However, the review process does incorporate cleaning and reprocessing validation of all devices. The agency is actively reviewing progress with the manufacturers and with the validation testing that they submit to FDA before the device is cleared.

Dr. Cardo added that DHQP works closely with FDA colleagues, who share the desire to improve medical devices.

Healthcare Antimicrobial Stewardship

Lauri Hicks, DO
Director, Office of Antibiotic Stewardship
Medical Director, Get Smart: Know When Antibiotics Work
Division of Healthcare Quality Promotion
National Center for Emerging and Zoonotic Infectious Diseases
Centers for Disease Control and Prevention

Dr. Hicks described efforts to improve antibiotic use in the community. CDC has worked in this area in the outpatient setting for a long time. The National Campaign for Appropriate Antibiotic Use in the Community was launched in 1995. In 2003, the program was renamed Get Smart: Know When Antibiotics Work. The new name coincided with a large media launch. The program's historical focus has been on acute respiratory tract infections (ARTIs), given that they are the conditions that lead to the most inappropriate antibiotic use in the community setting. The program is now considering other infections in dentistry and other areas that contribute to the overuse of antibiotics in the community setting.

The program aims to reduce the spread of antibiotic resistance by:

- Promoting provider adherence to appropriate prescribing guidelines
- Decreasing demand for antibiotics among healthy adults and parents of young children, which plays a major role in overuse of antibiotics in the outpatient setting because when providers perceive that a parent wants an antibiotic, they are more likely to prescribe it
- Increasing adherence to prescribed antibiotics

CDC has hosted Get Smart About Antibiotics Week annually since 2008. The goal of the observance is to increase the number of actively engaged program partners in the promotion of Get Smart messages to target audiences. The target audiences include:

- The general public
- Providers
- Hospital administrators
- Global interest groups
- Policymakers

CDC works with a number of partners on the observance of Get Smart About Antibiotics Week, including government agencies, state and local health departments, and international partners such as the European Centre for Disease Prevention and Control (ECDC). This year, the World Antibiotic Awareness Week, hosted by the World Health Organization (WHO), will coincide with Get Smart About Antibiotics Week, November 16-22, 2015.

CDC works with these partners on a number of issues beyond Get Smart About Antibiotics Week. One of the more successful and ongoing relationships has been with the Veterans Health Administration (VHA). They have been exploring appropriate antibiotic prescribing in outpatient clinics for some time. A recent published paper showed variability in prescribing across the VA outpatient clinics. Work has also taken place with the VA to implement clinical decision support to improve prescribing. Some of the implementation activities are being piloted in a number of VA clinics, with the goal of expanding across the VA healthcare system.

Professional societies have been important partners for many years. The American Academy of Pediatrics (AAP) released updated Principles for Judicious Prescribing in Pediatrics for ARTI in 2013. State and local health departments are being supported to develop and implement programs promoting appropriate antibiotic use in the community. Fifteen states were funded in 2015, but more than 30 states are participating in antimicrobial stewardship activities.

Corporate partnerships are an exciting element of antimicrobial stewardship. This year, Walmart issued a public service announcement (PSA) during Get Smart Week and beyond. The PSA reaches customers as they are in the checkout line at Walmart stores and will reach millions of individuals.

The program has also focused on measuring antibiotic use in the community. There are a number of resources for this measurement in the outpatient setting, including the following:

- CDC surveys, which help in the assessment of both the volume and appropriateness of antibiotic use:
  - The National Ambulatory Medical Care Survey (NAMCS)
  - The National Hospital Ambulatory Medical Care Survey (NHAMCS)
- The program has purchased proprietary data collected for pharmaceutical marketing, which has allowed for examination of antibiotic expenditures across the spectrum of healthcare and for study of population-based prescribing at the county and state levels based on the number of prescriptions filled
- Qualitative research has been part of the program since its beginning; changing practice in the outpatient setting requires that the messages resonate with the general public and providers
- Quality measure data (e.g., Healthcare Effectiveness and Information Set)
- Other data sources include claims datasets, National Health and Nutrition Examination Survey (NHANES) surveys, and healthcare system data

A great deal of progress has been made in the first decade of appropriate antibiotic use activities in the community. Data on antibiotic prescriptions resulting from doctor visits was collected for five conditions: Ear Infections, Colds, Bronchitis, Sore Throats, and Sinusitis. Assessing appropriateness can be difficult, but because antibiotics are never indicated for conditions such as colds or bronchitis, the percent of people who receive an antibiotic during a visit for those infections should be zero. Antibiotics are still being prescribed for those

conditions, but there have been incremental improvements in each of the five conditions of interest.

Antibiotic selection is an important aspect of stewardship. There is a great deal of macrolide and fluoroquinolone use for upper respiratory conditions. The most commonly prescribed antibiotic for bronchitis, which is not needed at all, is a macrolide. The most commonly prescribed antibiotic in the US is azithromycin. The indications for that drug are very limited.

Antimicrobial use should be considered across the spectrum of healthcare. Infections and antibiotic-resistant infections are a major concern in acute care as well as long-term care settings, and they are emerging increasingly in the outpatient setting. The majority of costs per year for antibiotics are in the outpatient setting: $6.5 billion of the total $10 billion that was spend on antibiotics in 2009 was spent in the outpatient setting. This spending does not represent use. Antibiotics in the outpatient setting are quite inexpensive. The outpatient setting represents approximately 80% of the total antibiotic use, but all settings are important. The bulk of the AR problems are in acute and long-term care settings.

The proprietary IMS Health data have been powerful in helping the program understand the national-level burden and volume of antibiotic use. In 2011, 842 prescriptions were written per 1000 persons in the community setting. Five out of every six people in the US receive an antibiotic every year. Not surprisingly, there is more use in the younger and in the older age groups.

The same data from 2011 allowed for the study of state prescribing rates. Kentucky has the highest prescribing rate in the country, with 1281 prescriptions written per 1000 persons. Alaska has the lowest prescribing rate, with 348 prescriptions written per 1000 persons. This variability in prescribing across the US needs to be understood, particularly given the uniform prescribing guidelines that are available. Based on preliminary analyses of conditions for which antibiotics are not indicated, there is more prescribing for those conditions in the areas with the highest prescribing rates. More needs to be understood about the other factors involved.

The program engages in policy activities, including quality measures and national goals. The Healthcare Effectiveness Data and Information Set (HEDIS) allows for analysis of provider-level prescribing for three measures of quality pertaining to antimicrobial use. It is not possible to use the data to learn about individual providers' prescribing practices, but it is possible to utilize health plan data. Employers also use these data to assess quality measures of the health plans. There is variability in performance on these measures across health plans. There may be opportunities to work with high-performing plans to learn lessons and to target low-performing plans. CDC is collaborating with Pew Charitable Trusts and an expert panel to establish national targets for reducing inappropriate antibiotic use. This initiative will be important for the agency, as the field is asking for a goal in this area.

A number of lessons have been learned in two decades of activities in appropriate antibiotic use, including the following:

- Start with measurement of antibiotic use and research. Data are needed for action.
- Tailor messages to specific target audiences. Patients as well as providers are targeted because of the role that patients play in this problem by putting pressure on healthcare providers to prescribe.
- Develop a partnership network and leverage support through effective partnerships.

- ❑ Support local-level intervention programs, such as programs with state health departments, the VA, and other health systems.
- ❑ Develop national policies that will facilitate implementation.
- ❑ Changing behavior and culture takes time and perseverance, as well as work with a variety of different partners.

Discussion Points

HICPAC observed that according to the map, states where antibiotics are overprescribed are also states where opiates and proton-pump inhibitors (PPIs) are overprescribed. The problem is likely to be larger than antibiotics, and it should be determined why providers in these states prescribe more medications.

Dr. Hicks pointed out that the maps depicting problems with overprescribing other drugs look the same as the antibiotic over-prescription map. They also look the same as the obesity map. There has been discussion regarding whether this overlap represents a causal relationship between the overuse of antibiotics in those areas, or whether the obesity problem is leading to a need for more antibiotic use.

HICPAC wondered about issues related to states with large rural areas and limited access to care. The more populated areas in these states may have the same high rates as other, more populated states.

Dr. Hicks said that the program has conducted an analysis of urban versus rural environments. The analysis did not identify differences between the urban and rural areas, but more needs to be done to examine that question more closely.

The literature about antibiotics refers to side effects. The relationship between the microbiome and obesity may be powerful, if antibiotics increase the risk of obesity.

Dr. Hicks said that the program is discussing this issue. Their first step is to focus on adverse events, particularly regarding *Clostridium difficile* (*C. diff.*). If there is an impression that antibiotics are linked to weight gain in children and adults, it will serve as an incentive to avoid them when they are not necessary. The program should consider how to incorporate the microbiome messages into the larger program.

The National Institutes of Health (NIH) seconded that idea and encouraged the pursuit of aspects of the microbiome. The map provides a significant epidemiological opportunity to work with microbiome partners to learn something at the macro level.

Regarding the bar graph that analyzes by age group, the American College of Occupational and Environmental Medicine (ACOEM) offered the interpretation that the more people interact with doctors, the more antibiotics they are prescribed. If the data are analyzed using a population denominator versus physician visit denominator, do all states track together? The conclusion of this analysis could guide where interventions are directed and whether interventions should only be done with physicians or with the general population as well.

Dr. Hicks added that females receive antibiotics much more frequently than males, likely because females have more interaction with the healthcare system, particularly during childbearing years. These data can help the program understand the audiences who should be

targeted. There is also discussion regarding how to prevent unnecessary visits in the first place. When a patient visits a provider, the provider assumes that the patient wants something.

HICPAC was curious to see how the data change as care models move toward electronic visits and asynchronous care. Prescribing practices may look different when patients interact with providers via Face Time or other technologies.

Dr. Hicks replied that the program is talking to Kaiser Permanente about the work that they have done in this area. Kaiser has a call center that allows patients and parents to call in. The staff at the call center work through an algorithm to determine whether callers need to seek care. There are concerns that telemedicine could potentially lead to a situation in which providers are prescribing without actually examining the patient. When a patient or parent can be guided regarding when to seek care, it may be possible to reduce inappropriate antibiotic use.

The overlap of opioid and antibiotic use is important to consider in efforts to educate the public. There are commercials airing on television for opioid-induced constipation medicine. Opioid use is becoming mainstream. HICPAC wondered about PSAs or other means for reaching audiences who are seeing commercials for these drugs.

Dr. Hicks said that the program works with a variety of partners that can help counteract that kind of messaging. Unfortunately, it is expensive to air PSAs on network television. It is important for CDC to be proactive in making sure the correct messages are being shared. Walmart is reaching an incredible amount of people with the PSA in their stores. In another example, a state worked with the airlines to play a PSA about appropriate antibiotic use as planes depart.

The Council of State and Territorial Epidemiologists (CSTE) said that at the state level, Tennessee is working with substance abuse staff to understand how closely opioid prescribing is related to antimicrobial usage and the geography of that relationship. The Get Smart program could work with the substance abuse elements of CDC to find synergies in understanding the underlying culture behind use. There may also be opportunities to collaborate in messaging.

Dr. Hicks replied that the opioid problem is public and well-recognized at the moment. CDC started working on the problem of opioid overprescribing and access relatively recently. The groups working on opioids at CDC have come to the Get Smart program for lessons learned from its work since the late 1990s and early 2000s to apply to their program and campaign activities. Even though the groups work in different areas, they should work together.

Consumer's Union commented that the pharmaceutical data are granular enough to identify the healthcare providers who are overprescribing. It makes sense to target populations, but it makes more sense to target the individuals who are overprescribing and to understand why it is happening, as well as the situations in which it is happening. Sometimes public disclosure is the most effective means for affecting change as it puts providers who are inappropriate prescribers in the public eye. It is a delicate area, but after decades of dealing with this problem, it is time to stop procrastinating and determine what/where the problems are and address them.

Dr. Hicks said that the program would like to go in that direction, but it is difficult. Other partners are able to assess individual provider practices and target them for education. The partners are also able to identify outliers. Kaiser has been making that information somewhat more public by having the poor performers, the outliers who are not prescribing appropriately, meet with the high performers. She has talked with colleagues at the VA about the possibility of using a model similar to this one in that system.

The VA is a good place to pilot such an initiative. The VA further said that if a patient sees a provider and has been sick for two weeks, he or she wants to get better. If they do not receive antibiotics, what are they getting? The current trend is to prescribe an opioid and steroids, both of which also have consequences.

HICPAC said that as providers are analyzed, care models and practice structures should also be analyzed. Which providers are in medical homes, and how much does prescribing replace high-touch interaction with patients in a different model?

Dr. Hicks said that there has been discussion regarding how behavioral interventions can make a difference in terms of patient-provider interaction. CDC needs to provide better tools for providers and the right tools for patients to facilitate that appropriate interaction. Providers overestimate the frequency with which patients want an antibiotic.

Antibiotic Use Data Update
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Dr. Srinivasan updated HICPAC on measures. The Standardized Antibiotic Administration Ratio (SAAR) has moved forward with the National Quality Forum (NQF). There was a public comment period. DHQP responded to the comments, which were generally positive and had a theme that the SAAR is important and needed. There were comments about the types of risk adjustment that need to be made and calls for more data on which to base the risk assessment.

DHQP has been working in partnership with Pew in a group focused on measurement and national goal-setting. During the group's most recent meeting in September 2015, they spent a great deal of time talking with different health systems that report data into the antibiotic use (AU) option of NHSN. They have received their SAAR calculations and are providing input on the data. The discussion was eye-opening, as they allowed the group to see the data and spend time thinking about how they might act on it. Both healthcare systems agreed that the data point them to items that are actionable. The systems had feedback about different ways to display the volume of data. The systems had employed various graphical systems for displaying the data. DHQP will continue to work with them. It is hoped that the SAAR will be part of the NHSN module soon. The goal is that facilities will be capable of calculating their SAARs in early 2016.

One of the healthcare systems was engaged in a performance improvement project on antibiotic stewardship while data were being collected using the SAAR measure. There were indications that hospitals have implemented good activities related to stewardship and have been active in trying to improve antibiotic use saw their SAAR measures decrease. It is important that the SAAR measure is sensitive to improvement.

DHQP is working on the annual facility survey for NHSN. It now includes questions on antibiotic stewardship programs. The data are available on the state level, with the percentage of hospitals in each state that report having an antibiotic stewardship program that incorporates all seven of the CDC Core Elements for Hospital Antibiotic Stewardship Programs.

There is variability in the map, but it provides data for action. California is predominating with 58% of hospitals reporting having a complete stewardship program. The data show high performers and low performers, and where efforts may be targeted. The data come at an important time as states move toward taking more active roles in preventing AR. Antibiotic stewardship is a large part of that effort, and states can use the data to work with hospitals to improve compliance with stewardship programs.

CDC's Core Elements for Antibiotic Stewardship Programs lay out high-level infrastructure and activities that have been associated with successful stewardship programs. Hospitals have provided feedback that they generally like the core elements, but they are challenged regarding how to implement them and what the elements might be in their individual facilities. Hospitals want to know the ways in which the elements can be implemented, and which ways are good, better, or best. They also want to know about barriers to implementation and how facilities overcome them.

DHQP is trying to provide more substance to the guidance. One of the approaches is through the National Quality Partnership, part of the NQF. The National Quality Partnership has assembled an Action Team for Antibiotic Stewardship that draws from the large and broad membership of the NQF, which represents the spectrum of different stakeholders in healthcare. They support the idea of developing a "playbook" for antibiotic stewardship. NQF had a similar activity focused on reducing early elective deliveries, which is a parallel problem to antibiotic overuse—there is too much of it, and there is guidance on how to make it happen less, but it is not supposed to be zero. The playbook for early elective deliveries was intended to be guidance for hospitals to talk about the different interventions that have been successful in reducing early elective deliveries, what implementation of those interventions looks like in a variety of healthcare settings, and the barriers that people encountered in implementing the interventions and how they overcame them.

The antibiotic stewardship playbook will be built upon the CDC Core Elements. It will help hospitals implement stewardship programs and provide examples. It can also serve as a model to inform survey and accreditation organizations. There is interest from regulatory and accrediting groups in thinking about requirements for antibiotic stewardship, so there will have to be a sense of what it looks like. The playbook can conform that education to groups that accredit hospitals. The Joint Commission has expressed interest in the playbook as well.

DHQP is partnering with health departments to advance stewardship. The division has provided funding to a number of states to start integrated antibiotic stewardship programs. They are working to help health departments, as this activity is new for some of them. There have been discussions regarding developing a technical package with information about what has been successful in health departments in improving antibiotic use and reducing antibiotic resistance.

The division has also been active in long-term care settings. In September 2015, the division released the Core Elements of Antibiotic Stewardship for Nursing Homes. They are similar to the core elements for hospital antibiotic stewardship programs. Experts in the area felt that while the elements are the same, their implementation is very different in a nursing home than in a hospital. The launch of the nursing home elements included checklists, appendices with implementation and measurement suggestions, fact sheets, and an infographic.

The engagement of nurses in antibiotic stewardship in hospitals has been discussed by HICPAC before. Thanks to some HICPAC members and liaison representatives, DHQP has connected with several nursing organizations. The division hopes to assemble a group of nurses to provide advice on the role that they can play in antibiotic stewardship. The American Nurses Association (ANA) has put out a call for nurses who are active in acute care hospitals who are interested in stewardship. Already, 50 people have responded to the call.

DHQP invited HICPAC's thoughts and guidance regarding how to improve guidelines for treatment of infections so that they consider stewardship more thoroughly than they do now.

Dr. Hicks said that their deliberations so far have focused on how guidelines inform many of their stewardship activities and interventions. In order to generate a solid set of recommendations, it is important to think about how guidelines for treatment of infections are developed and how those guidelines should incorporate elements of antimicrobial stewardship.

Guidelines establish standards of care, help identify where quality improvement is needed, and improve patient outcomes. Get Smart has helped develop clinical practice guidelines, primarily in collaboration with professional medical societies. Historically, the emphasis has been on respiratory infections because those are the areas that experience the most inappropriate antibiotic use. The program has developed guidelines for both adult and pediatric patients. There are challenges, as many guidelines are developed without consideration for their impact on the treatment of other infections.

The program has worked with AAP, which has taken leadership in this area. AAP developed guidelines related to the treatment of acute otitis media and were one of the first organizations to consider how antibiotics are prescribed and to incorporate principles of antimicrobial stewardship in their guidelines. The acute otitis media guidelines include the concept of watchful waiting for mild cases of ear infection. Get Smart worked with AAP on the document entitled "Principles of Judicious Antibiotic Prescribing for Upper Respiratory Tract Infections in

Pediatrics." This document applied principles of antibiotic stewardship to the existing guidelines. Every guideline could engage in a similar exercise.

Not only are there problems associated with antibiotic overuse for conditions that do not warrant them, but also there are problems associated with ordering tests that are not necessarily indicated or may have issues with interpretation if they are not ordered in the right circumstances. One of the most important elements of the diagnosis of acute pharyngitis and the determination of whether a patient has group A streptococcal (GAS) pharyngitis is to ensure the test is ordered at the right time. A test performed on a person who does not meet the criteria may yield a positive result in a person who does not have GAS.

Another component of this work is weighing the benefits versus the harms of antibiotics. It is important to think about the potential adverse events or consequences when antibiotics are used when they are not needed, or when there is little to no benefit. Providers should think about how to implement judicious prescribing practices. If an antibiotic is indicated, then options should be considered to decrease the total volume of antibiotic use to which that patient is exposed. Some organizations are thinking about these issues, but in many situations, the incorporation of stewardship recommendations or considerations would help positively impact and contribute to antibiotic treatment across the full spectrum, not just focusing on one illness or infections.

Discussion Points

CSTE asked when the playbook and technical guidance for state health departments will be available. Dr. Srinivasan hoped that the playbook would be on a rapid production schedule, perhaps in a six-month timeframe, if realistic. The first meeting will be held in December 2015. Many groups will be involved, so the process may move more slowly, but the product will be better for having the involvement of many groups. CDC has emphasized the need to work rapidly. Regarding the technical package, they are working with the Public Health Foundation to move forward as fast as possible.

CSTE suggested making parts of the playbook available as soon as possible. For example, providing guidance or examples in leadership in portions will be helpful.

HICPAC asked about collaboration with Choose Wisely in Canada. That group is more broadly focused than just antibiotics, but has similar resources and has developed collaborations with professional organizations.

Dr. Srinivasan answered that the program has worked a great deal with Choosing Wisely, both in visits and through professional societies. A number of Choosing Wisely recommendations are related to antibiotic use, antibiotic stewardship, and HAIs. SHEA recently submitted five items to Choosing Wisely related to the inpatient elements of stewardship. Previously, Choosing Wisely was more focused on outpatient conditions. The theme of limiting overuse resonates.

IDSA observed that this work is important. As the notion of incorporating stewardship language into guidelines progresses, CDC is encouraged to think broadly. There are many more professional societies than are represented as liaisons on HICPAC. Involvement from different procedural specialties will broaden the audience for the materials so that messages come from more than usual groups. It is encouraging that the playbook will include "good, better, and best" examples. There is tension in stewardship programs because leadership often depends upon availability. The core document highlights the role and opportunity of hospitalists who demonstrate success in performance improvement, but the "good, better, best" approach offers the opportunity to indicate that "best" is leadership from an infectious disease (ID)-trained, experienced professional who is already demonstrating performance improvement. Other individuals are suitable as well if such an individual is not yet available.

Dr. Srinivasan acknowledged that it is unrealistic to say that leadership has to come from an ID doctor, because they are not available in large percentages of healthcare settings. This issue relates to the ID community demonstrating its value. When a hospital's administration considers starting a stewardship program, the first thought should be to have an ID-trained doctor, although some experts in ID may not want the ID practice to lead stewardship efforts. IDSA takes stewardship education seriously and is making it part of the core training for ID. Discussions have begun with the playbook team regarding how to incorporate language about ID training.

IDSA said that the playbook is an opportunity to recognize the practicality of what is available now, and also to set an aspirational vision. In many aspects of medicine or clinical care, the singular qualification to take on a specialized task is availability. The industry can be driven in the right direction by encouraging leadership from people who have been trained in ID and have demonstrated how to use it effectively.

Dr. Srinivasan said the types of models can be expanded. For example, there are ID practices that do this work remotely. Alternative delivery models may be helpful for this specific expertise. This work does not dictate prescriptions for individual patients; rather, the work focuses on establishing a system. Much can be done to bring expertise to bear and to emphasize that there is a group of professionals with specific training that will be helpful.

HICPAC supported the three principles. The more concrete tools that can be provided to the many professional societies to include antibiotic stewardship principles in their guidelines and recommendations at a granular level, the better. A proactive approach may be to reach out to the professional societies and to provide them with those tools and principles. The societies can

be asked for commitment from their guideline committees to utilize the principles and to provide feedback. In addition to guidelines, it may be useful to work with groups that create quality metrics. Quality metrics may be released for sepsis or community-acquired pneumonia that could have unintended consequences of excessive antibiotic usage.

Dr. Cardo asked whether HICPAC should consider drafting a guidance document to help professional organizations when they are creating treatment guidelines. She asked the liaisons how their organizations approach stewardship in their guidelines. HICPAC and the liaisons can have significant impact in driving guidance development.

HICPAC was encouraged that the Get Smart program is now incorporated into DHQP. It is hoped that the state-level efforts will be stronger because of new collaboration opportunities with the consolidation. Regarding the California data, the state law requiring hospitals to have stewardship programs was passed in the fall of 2014. The programs had to be in place by July 1, 2015. The state law does not align exactly with the seven CDC core elements. It is important for the message to be shared that hospitals in California will be measured against the CDC elements, regardless of what is in the state law.

HICPAC was pleased to hear about the involvement of nursing groups. Hospitals are asking for a checklist or algorithm to accompany guidelines to make it easier to have quality improvement teams with people who may not have all of the clinical expertise but who can find basic areas on which to focus, such as the two or three antibiotics with the highest inappropriate use. Any formal guidance that HICPAC can provide regarding the elements that are needed for the guidance would be helpful so that the professional associations can take it upon themselves to develop guidance based on published documents.

HICPAC emphasized that the testing aspect of stewardship is important. The American Society for Microbiology (ASM) or the Clinical and Laboratory Standards Institute (CLSI) could be useful groups. For example, there is no guidance or standard regarding a positive urinalysis (UA) to drive a culture.

CSTE said that it is important that all groups speak with a common message from the same playbook. The Joint Commission Speak Up™ patient safety program states that antibiotics may be indicated for bronchitis. Mixed messages can be difficult to manage. Australia has strong antimicrobial stewardship guidelines, and all treatment guidelines have antimicrobial stewardship principles incorporated into them. The guidelines form the clinical decision support system and are used as the gold standard for appropriateness of antimicrobial use. The US does not have an equivalent. There may be a possibility of condensing the available research into a resource for what clinicians need to know, formatted with the three principles in mind. The resource could provide additional guidance regarding second-line or third-line antibiotics if regional prevalence of AMR is above a certain percentage. It would not be "one size fits all," but would take into account the different resistant patterns in a hospital or community. The Australian guidelines are endorsed by all professional societies. It would be difficult to create such a resource, but it would be ideal.

Dr. Hicks said that the program would like to move toward such a final product. The support of different professional societies will be needed for that approach.

SHEA and ISDA collaborated with other societies on the development of new guidelines on the implementation of antibiotic stewardship. The guidelines are likely to be well-received because of the number of societies that participated in the process. Other professional societies should be encouraged not only to offer guidance, but also to involve other groups in the development process to secure broad buy-in.

Dr. Diekema asked the HICPAC liaison members representing societies to raise their hands if their societies are promulgating antimicrobial use or treatment guidance. Three organizations indicated that they were in that process.

The Association of State and Territorial Health Officials (ASTHO) expressed concern about the percent of hospitals reporting that they have implemented the core elements. The core elements are subjective enough that there is likely to be a wide range of what is meant when hospitals say that they are implementing them. This area needs more scrutiny.

Dr. Srinivasan agreed. The program is addressing the issue in a number of ways. The questions on the survey are worded such that they are not checking a box. There are seven elements, but the survey has 15 or 16 questions that address whether a hospital is active related to the elements. The program is engaged in validation as well, as experts in stewardship are assessing the answers. The few places where validation has been conducted have had good correlation between the answers on the survey and the reality of practice, both for hospitals who said they had the elements and for hospitals who said they did not. More validation needs to be done.

Dr. Cardo said that the data are not perfect, but they are useful for knowing not just who has the seven elements, but who does not, and the common elements that hospitals do not have. This information allows the program to be more proactive. If hospitals do not have certain elements because of a lack of training and education, then CDC and professional organizations can be proactive to address that gap. If a hospital does not have feedback to clinicians, it may not have good data. The surveys are a starting point for improving stewardship programs.

Dr. Michael Bell (Deputy Director, DHQP) agreed that the survey has low bars and was struck by the number of facilities that have still not managed to achieve them. There is a great deal of work to do to reach the targets. Parallel to that work is the recognition that validation and precision are also necessary.

Consumer's Union has been calling for accountable antibiotic stewardship programs. There is concern that hospitals say that they have these programs but they are not measuring the progress. An accountable stewardship program would participate in reporting antibiotic use and AR infections to see if there are changes in those numbers.

Dr. Diekema emphasized the importance of the planned work on risk adjustment for the new SAAR metric. Many hospitals are concerned about any new metric, because they may eventually be used punitively against them. Overall, however, the effort is a positive one. There is work for HICPAC in playing a role in providing a product related to guidance for guideline development that related to antimicrobial utilization. There are examples of frameworks available.

Nontuberculous Mycobacterium Infections Associated with Heater-Cooler Devices

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Dr. Perz reviewed points about Nontuberculous Mycobacterium (NTM) and infections associated with heater-cooler devices.

NTM are relatively slow-growing bacteria clinically in terms of how long it takes infections to develop as well as in terms of culturing, analytics, and diagnostics. The organisms are ubiquitous in the environment and are opportunistic. As such, transmission is often recognized in the healthcare setting. The healthcare setting presents a combination of one or more of the following:

- ❑ The presence of immunocompromised patients
- ❑ Breaches in normal host defenses, such as incisions, injections, and vascular access
- ❑ Novel exposure pathways, often involving water.

The October 23, 2015 *Morbidity and Mortality Weekly Report* (*MMWR*) reported an investigation of eye infections of *Mycobacterium chelonae*. Four patients acquired infection after laser-assisted in situ keratomileusis (LASIK) surgery in an ambulatory surgery center (ASC). The source was identified as a misting humidifier that was contaminated with the same organism. There was a pulsed-field gel electrophoresis (PFGE) match between patients and the humidifier isolate. The clinic's purchase of the consumer-grade humidifier was motivated by the need to maintain a specific level of humidity for the laser device. The clinic was not aware of the American Society of Heating, Refrigerating, and Air-Conditioning Engineers (ASHRAE) and HICPAC standards indicating that use of a stand-alone humidifier in this manner is not advised. Given that this event occurred at an ASC, there may be opportunities to work with colleagues at CMS and accrediting organizations to check for lapses such as this one. If LASIK procedures occur in a non-certified setting, the work will be more challenging. CDC is preparing outreach to the user community in the coming weeks.

An outbreak of invasive *Mycobacterium* (*M*) *chimaera* infection following open-heart surgery patients was reported in the July 2015 issue of *Clinical Infectious Diseases* (*CID*). Investigators in a Swiss hospital identified six cases of invasive *M. chimaera* in patients who had received implants as part of their open-heart cardiac procedures. The investigation focused on possible water sources, since the outbreak was of an NTM infection.

Particular focus was on the heater-cooler unit. These units are used with heart-lung machines, oxygenators, and cardioplegia devices. They are approximately 30 inches tall and have up to three circuits that provide temperature-regulated water to either the oxygenator, a blanket that is used to regulate a patient's temperature, or to the cardioplegia solution or device. All of the circuits are closed and do not contact the patient directly. In all three cases, they contact another device. The Swiss investigators identified *M. chimaera* in the internal heater-cooler water circuits on the device and in air samples that were obtained when the device was running. The air samples were negative when the device was not running.

Two fans are present in the heater-cooler. This design is typical for this class of device. One fan cools the device's internal components, and another, larger fan draws air into the machine. While the water circuits are self-contained, the possibility of water escaping the circuits should be considered, particularly given that the device has an overflow bottle in front of the grill where air passes.

The investigation began in 2012 after the first two patients were recognized with the unusual NTM species. Prospective surveillance identified four more patients, two who became evident in early 2013 and two more in early 2014. The investigation considered the heater-cooler unit as a potential source of the pathogen. The hospital decided to replace their machines. Within a few months of the installation of the factory new units, they were also growing *M. chimaera* from the tank water, despite careful attention to the maintenance and disinfection of the units.

FDA posted a recall notice from Sorin, the manufacturer of the unit from the Swiss outbreak, in July 2015. In June 2015, Sorin USA had issued a field safety unit. The FDA recall acknowledged the receipt of evidence that while water is not intended to contact the patient directly, there is potential for aerosolization and subsequent exposure of the surgical site. The recall did not replace the units; rather, it called for replacement of the instructions for use, including cleaning and disinfection.

On July 20, 2015, the Pennsylvania Department of Health was notified by a hospital of a cluster of NTM infections among cardiac surgery patients. The hospital became aware of the heater-cooler reports and realized that several patients that had previously undergone cardiac surgery at the hospital had infections that were only identified at the *M. avium* complex (MAC) level. That complex includes *M. chimaera*. The investigation included CDC and the Pennsylvania Department of Health, with full cooperation by the facility. Because of the previous association and the realization that the heater-cooler units might be a factor in the outbreak, they were replaced immediately upon identification of the cluster and consultation with the department of health.

Ultimately, the investigation identified eight cases of invasive NTM. Three cases were identified as *M. chimaera* and the rest were at the MAC level. Those patient specimens were no longer available. There is a long latency period of the infection. The time between surgery and the infection diagnosis in the *CID* report was over three years for several patients. A similar trajectory was observed in the Pennsylvania investigation, which experienced a multi-year delay between the presumptive exposure and diagnosis. The development of symptoms was not necessarily on a similar delay.

Preliminary epidemiologic and laboratory findings point to the heater-cooler unit as the source of the NTM. The investigation is ongoing and is led by the Pennsylvania Department of Health. *M.*

chimaera was recovered from the heater-cooler units that were removed from service. Work is ongoing to analyze the PFGE patterns among patient isolates and isolates from the devices.

The investigation is public. Even with preliminary results, there was a sense of urgency that the findings were important to share, especially with the patients. The Pennsylvania Department of Health has communicated about the issue, and the hospital has conducted strong communication work with patients and medical professionals, recognizing the importance of encouraging clinicians to think of NTMs in these situations. FDA has also communicated on this issue, posting a safety alert on October 15, 2015. The alert is not specific to one manufacturer. Based on reports that FDA has received and on ongoing investigations, there is reason for concern about the class of devices in general. The recommendations from FDA include the following:

- Adhere to the current manufacturer instructions, being cognizant of recent recalls that updated the instructions
- Utilize sterile or filtered water; however, different manufacturers have different advice regarding whether sterile water is compatible with the device
- Direct the exhaust from the device away from the sterile field
- Remove units that show signs of contamination
- Engage in MedWatch reporting of infections that might be associated with these devices and of concerns about the device instructions or presence of contamination

Sorin has recommended locating the unit physically farther away from the sterile field. The positioning of the unit is limited because of the length of the available tubing and performance characteristics of the device.

CDC has also engaged in outreach on this issue. The healthcare community receives many useful notices regarding recalls and alerts from FDA, but this case represents more than a hypothetical risk: there are real infections present and evidence of occurrence in the US. CDC's aim has been to amplify the FDA alert to reach a broader swath of targets, including public health departments; hospitals; clinicians; and patients.

Dr. Bell said that learning of an event such as this outbreak presents an opportunity to ensure that no one else is exposed. Additionally, the event raises questions regarding what to do about the people who have been exposed. The denominator is substantial. The number of procedures performed using these devices that are essential for lifesaving surgeries is high. Many procedures using these devices occur without negative outcomes. Detection of this cluster is due to clinicians' awareness and thoughtfulness. This situation is not a massive crisis, but it is an indication that much is undetected in the patient care environment.

The response to this outbreak is an effective example of a state health department and a facility reacting appropriately and getting appropriate partners involved quickly. Taking the affected machines out of circulation immediately was a good strategy. There is not a straightforward answer regarding how to move forward with these machines

Outreach to potentially involved patients and others has taken place in a short amount of time. These efforts began with the usual groups of healthcare epidemiologists and infection control colleagues to ensure that there is awareness of the issue throughout the hospital. There is also an immediate need to talk to individuals who manage operating theaters to make them aware of the situation. Materials management and the hierarchy of facilities management are also involved. Groups that have experience in what happens in an operating theater, such as the Association of periOperative Registered Nurses (AORN) and profusionist groups have been involved. Outreach has also taken place with other clinical colleagues. The devices are used not only for heart surgeries, but also in other procedures such as liver transplants. This indolent infection presents with non-specificity. It can present as a suppurative surgical wound, or it can also be a deeper infection with non-specific symptoms such as fever and failure to thrive. There are significant in correct diagnosis. Outreach can mitigate the delays, as clinicians with patients who might have been exposed are thinking about NTM as a possibility.

CDC also convened professional groups of individuals who care for NTM-type patients to ask whether there are simple and effective measures to offer patients who might have been exposed. The short answer is that there are not, partly because antimicrobial choices change dramatically based on the species. Additionally, if the infection is recognized appropriately, the treatment is generally manageable and successful. The benefit of post-exposure prophylaxis is therefore unproven and may have adverse consequences (including antibiotic resistance emergence).

The heater-cooler unit appears to be harmless from an infection perspective, but the water overflow bottle is likely rarely, if ever, sanitized and is situated in front of a fan. Nothing that blows air should be in an operating theater, if possible. That risk assessment approach is not built into these devices. The Swiss facility moved the machine outside the operating theater on the other side of a wall. There are concerns about trip hazards from longer tubes and less effective operation because of the dissipation of heat, but it is important not to blow air in the operating theater. In looking inside the machine, it is clear that a reservoir of warm water in a steel container in a chilled operating theater will have condensation that will drip. The insulation layered inside the machine is a non-cleanable foam. The situation is perfect for growing all manner of organisms, not just NTMs. NTMs happen to be durable and noticeable enough to be identified as a surgical case cluster, but there could be other organisms as well. There could be protection for patients from perioperative prophylaxis, which could mask the other organisms.

This experience regarding devices raises the questions: What are the unintended infectious disease risks related to devices in surgical settings? How cleanable are the devices?

The cleaning and maintenance instructions for the heater-cooler unit focused on the basin and the tube of circulating water. These elements are not likely to be the primary culprit for the organism growth. It is more likely that other factors contribute to the problem. The opening for refilling the reservoir is approximately two inches in diameter, leading to the likelihood that water is likely to spill over the edges. There is non-cleanable insulation within the device. The large cooling fan at the base of the device and louvers on the side of the machine contribute to chaotic dispersal of potentially contaminated air.

More infections have not been observed, probably due to good practices within operating theaters, such as air exchanges. The devices are not likely to be pointed directly toward the operative site. There may be concerns associated with the smaller cooling fan that blows air out of the device because it is closer to tables that may hold sterile equipment.

A systematic review of practices should be engineered to determine these issues. Currently, such a review is not part of anyone's job responsibilities. Materials management follows the manufacturer's instructions for cleaning. The operating room staff, surgeons, and infection control personnel do not perform this kind of risk assessment. It is likely that another device will be discovered to be problematic. Consideration must be given to what must be done in advance for the next series of devices. Also important to contemplate is how industry should be informed about expectations as devices are being designed, not from a regulatory perspective, but from a microbiologic, patient safety perspective. An approach that provides design considerations for patient safety may merge well with the regulatory aspects of medical device development.

Discussion Points

Dr. Cardo thanked Dr. Diekema and Dr. Yokoe for their rapid response in helping to identify experts to address questions regarding prophylaxis. She thanked the HICPAC liaison representatives who were also responsive to the calls to expand the partners who have contributed to this work.

Dr. Bell added that the American Hospital Association (AHA) helped CDC make connections. Laboratory staff from CDC visited the hospital sites and were able to collect samples to make a direct connection between the devices and the infections in patients.

Regarding the recommendation on using sterile water, HICPAC asked about consideration of treating the water with chlorine or otherwise.

Dr. Perz replied that the topic of treating water is challenging due to the potential for corrosive effects and various incompatibilities. FDA is working with manufacturers to bring more clarity to the question. The current, generic recommendation is to place a .22 micron filter on the water source that is used to fill the unit.

Dr. Bell was skeptical about sterilizing the water as a solution to the problem. Sterile water may go into the basin, but the basin is open to the environment and there is persistent wetness within the circuit, so there will be organisms. Sterilization will also not answer the question of condensate pooling in the device. The problem centers on maintenance of the device and

cleaning it between uses. However, the device is not designed to be cleaned in the areas that it needs to be.

HICPAC thanked CDC for the communication of October 27, 2015. As more information is gathered, it might be possible to be more specific about the recommendations for evaluating patients who might have an infection. The window period is long, and the potential manifestations of illness are wide-ranging. More specific guidance would be helpful for identifying additional cases.

HICPAC asked about the possibility of putting a filter on the outside of the fan so that the air is filtered and not expelled strongly into the air in the operating room.

Dr. Bell indicated that the manufacturers could answer that question. He hoped that there would not be makeshift solutions to devices around the US. If improvised solutions reduce the efficiency of the device, there will be unintended consequences. Putting the entire unit in a sealed box with a separate exhaust management system is a post hoc solution that has been used in Europe.

The VA expressed concern that this issue may be a small component of the larger problem of hospitals, hotels, and other facilities adding supplemental chlorine to water. As chlorine is added, the less virulent organisms are killed off, and the NTMs are more resistant. The total number of organisms may well be rising. Infections with NTMs are increasing, particularly regionally. After the clusters of Legionella in the US, many people are chlorinating their water, including in Pennsylvania. The thought that the NTM outbreaks associated with devices may be a sentinel event is worrisome.

Dr. Perz welcomed that point and noted that it seems that CDC is conducting more NTM investigations generally. In addition to the example of the ASC, CDC has been assisting a state with an investigation in a dental setting. It is important to think about water and both direct and indirect pathways. The variation among how municipal water is treated and how hospitals may be doing supplemental treatment is worth more attention.

There are many overlaps between this issue and the issue of contaminated duodenoscopes. Both issues reflect design problems with the medical devices on which the field has become so reliant. Practice changes are "Band-Aids." The primary concern is the design of the equipment. The resolution will require redesign. There should be strategies for pushing those redesigning priorities forward. Depending upon strategies such as noticing when equipment is contaminated is a suboptimal approach.

Dr. Cardo hoped to hear more from HICPAC on this question. DHQP hopes to identify the problems with medical devices, which are often designed creatively but without consideration of infection risk and cleaning. Similar issues have emerged in environmental infection control. It would be helpful for HICPAC to think of strategies and approaches that each partner can employ.

Dr. Bell agreed that the suggestion for relying on visual inspection for a microscopic organism is not a good one. HICPAC and CDC can promote understanding that these organisms cannot be seen, even if contamination exists.

HICPAC supported the idea of setting general principles. There is no direct responsibility for risk assessment, but many professionals in infection prevention take on that responsibility. There can be a great deal of pushback when there is no conclusive evidence about an expensive piece of machinery or equipment that is vital to clinical care. Some problems are discovered through the course of unrelated investigations. A general set of principles highlighting water source and other issues would be helpful, as the burden of proof is always on the hospital epidemiology/infection prevention group to prove that there is a problem and to spur action.

An integral conversation should be occurring not only between FDA and the manufacturers, but also with CDC. The "Band-Aid to clean" has to come with the assurance that what is being proffered can be reliably implemented without extreme duress. For example, creating a chamber for the heater-cooler unit on the other side of a wall in the operating room seems to solve the problem from the manufacturing side, which will not need to make any changes if that step is taken. This problem is exemplified by the response to the device problem with endoscopes. There is extreme difficulty in cleaning the devices to the degree that it cannot be assured that they are clean. The responses to clean are appropriate interim solutions, as it is not possible to redesign devices quickly. The pressure to redesign, however, should be strong. The question of being able to clean reliably without an extreme onerous solution should be part of the planning process from the outset as opposed to after the fact, when there is an outcry from the field.

Dr. Diekema said that his hospital discusses the need for an industrial engineer who understands the principles of infection prevention, infection control, and organism transmission. The engineers who design these devices need a baseline understanding of pathogen transmission, environmental microbiology, human disease, and other relevant topics.

Dr. Bell commented on purchasing, which is the step between design and use. Someone who performs risk assessments should be involved at the purchasing decision point for health systems.

HICPAC could have a role in creating a guidance document to identify specific areas for consideration. AHRQ has a document for medical devices that focuses on issues related to how to take human factors and medical errors into account in the design process. The idea of filters was raised regarding suction in the 1980s when there were infection risks associated with devices that had a bag inside an outer, hard container that carried risk of contamination. Filters were also part of the suction systems in the walls. The Association for the Advancement of Medical Instrumentation (AAMI) held a risk management summit in conjunction with FDA that included discussion of partnerships with medical devices. A White Paper will be produced from that meeting, and it might be helpful to contact that group.

CSTE observed that in the design of instrumentation going forward, it would be helpful to provide industry with guidance regarding basic principles. If possible, it would be helpful for the FDA process to include individuals who are familiar with the hospital setting to conduct a risk assessment. Risk assessment should be conducted on the devices that are already in use. This process would be aided by an organized approach, rather than asking every facility to do the assessment. A few centers could make a concerted effort to look for risks rather than diffusing the effort across the healthcare system.

AORN commented on the importance of the product selection process and having an interdisciplinary team at the table for it. AORN has guidelines for product selection, but depends on infection preventionists to share their expertise and knowledge in making decisions. Clear guidance regarding product selection would be helpful to the team.

The Surgical Infection Society (SIS) noted that this problem is a physical plant question. A consistent source of high-volume, clean-but-not-sterile, hot and cold water is needed to drive these machines. These devices were created because hospitals were not built with that capability. Hospitals, particularly operating rooms (ORs), need better access to hot and cold water. A more centralized system would remove the need for fans in the OR.

APIC said that the charges from the document from Sorin and the recommendations from FDA for infection preventionists are very involved. The recommendations address sampling, cleaning, re-sampling, and performing air sampling, which is challenging. Because the guidelines are complicated, many hospital settings are turning to their infection prevention teams for assistance in operationalizing them. Additional guidance would be helpful, especially to smaller organizations that do not have a great deal of support. Regarding systemic surveillance, the recommendation was made to conduct a retrospective assessment. It would be helpful to know how many facilities have done that. The more feedback that is gathered, the more robust the body of information will be.

Dr. Diekema asked for an informal raising of hands of HICPAC members and liaison representatives whose hospitals have performed retrospective assessments. Approximately six to seven indicated that they had.

Intervention should occur earlier in the pathway. It does not make sense to place the burden on the end user. HICPAC urged caution regarding what is recommended regarding these important, severe, and rare infections. Thousands of other devices have complications that are more common. Focus should be on early prevention, not on encumbering the end user for surveillance, culturing the air, and other functions.

Dr. Bell raised the issue of routine culturing of devices, which is a non-starter for NTMs because their growth is so slow and because laboratory capability is limited. The manufacturers' literature may suggest that culturing should be done, but it is not possible. In addition to conducting the outbreak investigation, the laboratory is thinking of rational tools and alternatives that can be used to assess the general hygiene of a device that might have been wet. It is preferable that a device be designed appropriately, or that a system is created to accommodate a challenging device and disinfect it reliably without having to drive practices by repetitive sampling.

APIC said that manufacturers state that repetitive sampling should be conducted once devices are clean, and to continue to culture constantly while the heater-cooler unit is being used to ensure that it remains safe. This topic needs to be discussed, and recommendations should be made to healthcare organizations, infection preventionists, hospital epidemiologists, risk managers, and profusionists regarding how to proceed.

Dr. Perz reported that FDA and CDC are actively engaged in this conversation.

Regarding the different types of medical devices, FDA requires manufacturers to develop instructions for cleaning and maintenance, but there is a disconnect between having that information and how it is marketed. The devices are marketed to personnel who do not clean or maintain them. Manufacturers should be held more accountable for including details on device cleaning, reuse, and disinfection as they are marketing to providers, and ensuring that the purchaser of the device has the necessary equipment and accessories to appropriately disinfect and reuse it. There is opportunity to improve the marketing component in the clinical setting.

The Society of Critical Care Medicine (SCCM) addressed how HICPAC can have impact on this problem in the absence of additional FDA regulation or legislation. Guidance regarding a rating system for infection safety would be helpful in working with hospital value analysis committees. Many of SCCM's members are members of large-group purchasing organizations that could exert pressure in this area, but there is no tool available to support it.

Dr. Diekema said that it is problematic when there are no options, or limited options, for some devices, such as heater cooler units and duodenoscopes. This increases the importance of being proactive in review of new devices for potential infection risk prior to approval..

Update: Research Framework for Environmental Infection Control: Environmental Surfaces

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Dr. Reddy updated HICPAC on the draft research framework for environmental infection control. The focus of the research agenda is to establish shared goals and objectives for CDC and partners, as many of them are engaged in environmental infection control research. The primary focus of the agenda is on non-critical surfaces and the contamination of those surfaces.

The agenda begins with a focus on adult acute care settings, intensive care units (ICUs), and wards. There are important differences in different healthcare settings, and the agenda will broaden to understand environmental contamination in all of them. The aims of the research agenda are threefold:

1) Modeling Transmission: Understand the role of non-critical environmental surfaces in the transmission of pathogens in different types of healthcare facilities. This aim addresses how surfaces become contaminated, as well as how a pathogen may then be transferred to a patient. The aim also addresses the proportion of all HAIs that may be related to environmental surface contamination.

2) Measuring Cleanliness: Evaluate methods for measuring surface contamination, including sampling. Determine whether the total bioburden level should be assessed, or whether the focus should be on individual pathogen bioburden levels. Determine cleanliness thresholds associated with improved patient safety outcomes, such as transmission events.

3) Improving Cleanliness: Understand the current state of cleaning and disinfecting surfaces, including monitoring. Evaluate methods for reducing contamination in order to improve patient safety outcomes. Improving cleanliness focuses on process and the human factors that influence cleaning and disinfection in the healthcare environment. For instance, what aspects of the environmental service workers' workload impact their ability to do their work well? This question incorporates education and training in infection control principles as well as structural issues related to job turnover rates, bed turnover, and other influencing factors.

In September 2015, DHQP hosted Environmental Hygiene: Ebola and Other Emerging Pathogens in Healthcare, a one-day roundtable with speakers on the current state of knowledge in environment infection control and ample time to discuss the agenda. It is important to have shared objectives throughout the process of understanding more about environmental infection control. The attendees were a diverse group, including representatives from academia, industry, patient advocacy, and environmental services unions. The presenters were:

Dr. Curtis Donskey: *Patient microbial burden and its relationship to environmental contamination*
The talk discussed patient factors that influence shedding. For instance, antibiotic use may increase "super-shedders" and their ability to shed into the environment.

Dr. Mary Hayden: *Differences in environmental contamination by pathogen: Implications for assessment and transmission*
Certain areas of patient rooms are more contaminated than others, and these areas may vary by different pathogens. There are challenges associated with sampling different environmental surfaces.

Dr. Susan Huang: *Attributable risk of the environment? Important cleaning moments for monitoring*
Not enough data are available to answer the question of attributable risk, but an analogy for the problem is a series of unfortunate events, each of which carries probability.

Dr. Deverick Anderson: *Approaches and logistical challenges of clinical trials regarding environmental surface contamination*
Patient-centered outcomes are the goal, but there are many challenges associated with designing and conducting studies that assess them.

The robust discussion at the meeting included several points. Regarding modeling transmission, there is clear interest in understanding different healthcare settings. The group also discussed the role of air and water, which play a role in contaminating surfaces and colonizing patients. Portable devices such as computers on wheels and their role in transmission were discussed, as well as basic questions regarding who has responsibility for cleaning the devices. Manufacturers have specific recommendations for cleaning and disinfection of their devices, but the recommendations do not necessarily utilize the materials that are available at a given hospital. Room design plays a role in preventing contamination and simplifying cleaning and disinfection. In terms of improving cleanliness, human factors are important, and environmental services workers want to be at the table not just at infection control meetings, but at the table when implementation research and research into how to improve their work is planned. The group also discussed strategies as well as short- and long-term goals and priorities for environmental infection control research.

A summary of the meeting and agenda have been posted on the website. It is hoped that it will serve as a "landing page" for future projects as they are completed and a reference point for toolkits and other resources. DHQP is actively involved in all of the questions in the research agenda. The research agenda is not sequential. One study may consider multiple aspects of it. For instance, multiple projects are examining transmission dynamics or methods to improve cleanliness. Grantees and contractors are expressing a need to understand how best to sample the environment and some basic principles that should inform the decisions. The DHQP is engaged in discussing these issues so that the protocols are standardized and the studies can be repeated and compared to each other.

Discussion Points

HICPAC emphasized that a great deal of CDC-funded research uses environmental sampling, and the methods differ across studies. The work that DHQP is doing to standardize the approaches will be beneficial.

HICPAC agreed with the importance of clarity between the research role and the readiness for clinical implementation. Defining a target level of cleanliness, and how it can be defined, is important, as it is not rational to expect the environment to be sterile. While it is understandable that the agenda is not sequential, care should be taken not to leap ahead to improving cleanliness and setting goals before the best ways to measure and other key points, such as the level of cleanliness at which there is clinical impact, are understood. That threshold should be kept at the forefront so that the research does not follow directions that do not necessarily make patients safer and are not necessarily clinically connected.

NIH applauded this effort. NIH has struggled with CRE for quite some time and has been astounded at the extent to which the organisms are found, and may not be related to detectable clinical issues. The organisms are in sinks and sink drains all around the hospital, which has elevated concerns; however, there is no identified connection. The situation illustrates the lack of understanding of the healthcare-associated epidemiology of environmental organisms. DHQP's work in this area is important.

Considerations for Evidence-Based Evaluations for New and Evolving Proprietary Products for Infection Control

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Ms. Stone introduced the topic of approaches to evidence-based evaluations for new and evolving proprietary products for infection control. HICPAC's involvement in this area includes the focus on triclosan-coated sutures, as well as the need to update the recommendations on chlorhexidine gluconate-impregnated (CGI) dressings from the Bloodstream Infection (BSI) Guideline. Consistent, transparent, and reliable evaluations of proprietary products should be made to inform recommendations with an eye towards the evolving landscape of infection control products, their innovation, and evolution.

One of the recommendations in the 2011 CDC and HICPAC BSI Guideline Infections evaluated CGI dressings. At the time, the proprietary products on the market were a CGI sponge and a CGI gel.

This guideline was the last one to be grandfathered in before the current methodology. It was written using the previous methodology, along with a draft version entered into the federal register for a public comment period. Comments received during the public comment period indicated that the products should be evaluated separately. Comments specified that between the different chlorhexidine-impregnated dressings, the method of delivery of the chlorhexidine was different, the products were different, and there was more evidence for the sponge. At the time there was no evidence for the gel dressing. As a result, the two products were evaluated separately, with separate recommendations. The 2001 Guideline reads:

> Use a chlorhexidine-impregnated sponge dressing for temporary short-term catheters in patients older than 2 months of age if the CLABSI rate is not decreasing despite adherence to basic prevention measures, including education and training, appropriate use of chlorhexidine for skin antisepsis, and maximum sterile barrier (MSB) precautions. **Category IB**
>
> No recommendation is made for other types of chlorhexidine dressings. **Unresolved issue**

The first recommendation was a Category IB, based on one systematic review of sponge dressings and two RCTs of sponge dressings.

Recent work since the last time the chlorhexidine dressing update issue was presented to HICPAC in November 2013 has analyzed the two types of dressings together. The January 2014 Update to the SHEA Compendium of Strategies to prevent CLABSIs in Acute Care Hospitals is an implementation guideline that considers the different types of CGI dressings together. The dressings are addressed in the Special Approaches section. These special approaches are recommended for use in locations and/or populations within a hospital with unacceptably high CLABSI rates despite implementation of basic CLABSI prevention strategies. These measures may not be indicated if institutional goals have been consistently achieved.

> 2. Use chlorhexidine-containing dressings for central venous catheters (CVCs) in patients over 2 months of age **(quality of evidence: I)**
> a. It is unclear whether there is additional benefit to using a chlorhexidine-containing dressing if daily chlorhexidine bathing is already established and vice versa.

The supporting literature for the Level I Quality of evidence is one systematic review on sponge dressings, one RCT on gel dressings, four RCTs on sponge dressings, and one observational study on sponge dressings.

A recent meta-analysis, Safdar et al 2014, analyzed all types of CGI dressings together. The objective was to assess the efficacy of CGI dressings for prevention of CVC-related colonization and catheter-related bloodstream infection (CRBSI) using meta-analysis. Their primary analysis of 9 RCTs (8 sponge, 1 gel) with 5639 patients showed a reduction in the risk of CRBSI with chlorhexidine dressing versus all comparator dressings. The relative risk was 0.57 with a narrow confidence interval and low heterogeneity.

A Cochrane review was released in 2015 on dressings and securement devices for CVCs. Its objective was to compare the available dressing and securement device evidence for CVCs in terms of CRBSI, catheter colonization, entry- and exit-site infection, and a host of adverse events. CRBSI for CGI dressings compared with Standard Polyurethane (SPU) dressings in 5 trials (4 sponge, 1 gel) showed unclear evidence of reduction in CRBSI. The quality of evidence was moderate, with a confidence interval that spanned 1 and low heterogeneity. Additional analyses were conducted on the frequency of CRBSI for CGI dressings compared with all other dressings. That analysis included 6 trials (1 gel, 5 sponge) and showed a relative risk of 0.60 showing significant reduction in CRBSI with CGI dressings and low heterogeneity. The evidence was high-quality. The final analysis of CGI dressings was the rate of CRBSI per 1000 patient days. This analysis included 4 studies comparing CGI dressings with SPU dressings (1 CGI gel dressing, 3 CGI sponge dressing). The analysis showed significant evidence of benefit with a relative risk of 0.51 and a narrow confidence interval. The evidence is moderate-quality, downgraded for imprecision.

In light of these recent systematic reviews and multi-organizational recommendations, the Key Question for this recommendation has been updated as follows:

> *For patients older than two months with temporary, non-tunneled catheters how do CGI dressings, compared to standard dressings, impact the risk of catheter-related infections?*

The critical outcomes are, infection, such as CRBSI, catheter-related infection (CRI), or CABSI. An additional outcome considered is product-related adverse events.

The initial search strategy through August 2015, including references from the 2011 HICPAC guideline, was expanded through September 2015, with abstract and full-text reviews conducted by CDC. Based on the inclusion and exclusion criteria, 6 studies were incorporated into evidence and Grading of Recommendations Assessment, Development and Evaluation (GRADE) tables:

The studies highlighted in yellow in the table have received some form of industry funding. The studies highlighted in pink have chlorhexidine skin antisepsis. Those highlighted in green have alcohol skin antisepsis, and the yellow have povidone-iodine skin antisepsis. A study of 12 centers in France used either povidone-iodine or chlorhexidine gluconate (CHG) and did not delineate which centers did which. The studies highlighted in red contained adverse events as a predefined outcome. Some studies did not predefine adverse events, but mentioned that there were no adverse events. Three of the larger studies show decreased CRBSI and CRI, and three studies show no significant difference in the critical outcomes.

Regarding chlorhexidine resistance, one RCT suggested no suspicion of bacterial resistance to chlorhexidine dressings. Another RCT detected no changes microorganism profiles. None of the other studies reported on chlorhexidine resistance.

When this topic was last presented, HICPAC suggested taking a deeper look at product-related adverse events. A systematic literature search was conducted in September 2015. The search returned two case series of seven patients each. DHQP is working with FDA to explore the utility of Manufacturer and User Facility Device Experience (MAUDE) and MedWatch data for incorporation into the adverse events work and into the narrative summary.

DHQP would like to engage one or two HICPAC experts to review the analysis, GRADE tables, evidence tables, adverse events data, and draft recommendations for presentation at the next HICPAC meeting.

Questions for consideration include:

CGI Dressings

- ❑ Combining products: Are there any reasons not to combine CGI dressings?
- ❑ Outcomes to consider: Colonization data was initially deemed a proxy for infection data and was not incorporated. Should it be incorporated? Are there other product-related adverse events that have not yet been considered?
- ❑ Are there other considerations, such as other sources of adverse event data, that should be included?

New and Emerging Proprietary Products

- ❑ What products are similar enough to be considered in a product class? For example, when are CGI dressings similar enough to be considered together?
- ❑ Evaluating a new or emerging product or product class: Is there a temporal threshold for this work? Should it be done every two years, for example, or should the evaluation wait until a product has been on the market and in use for a certain number of years, regardless of RCT data? Should there be evidentiary thresholds? Is one RCT enough to evaluate a product and make a recommendation?
- ❑ Are there other factors to consider? For example, if clinicaltrials.gov is enrolling 10 trials, should that product be evaluated at that time?
- ❑ How do other organizations make recommendations for proprietary products?

Discussion Points

Dr. Diekema opened the floor for discussion and noted that HICPAC will have an opportunity to delve further into individual studies during the next meeting.

HICPAC did not see a reason not to consider gel and sponge dressings together.

Dr. Cardo said that it would be helpful for future decisions to understand the rationale for considering the products together.

Dr. Diekema agreed and noted that the rationale will address the broader question of when products are similar enough to be viewed together, and when they should be separated. He asked for comments regarding whether to expand the outcomes from the infection event to include line colonization data. Some studies in the literature consider colonization as well.

Ms. Stone clarified that typically, the studies analyze exit site colonization and catheter tip colonization.

If enough science uses the outcome of infections, then it will not be necessary to rely on colonization data, which is usually used when there are not enough studies or an inadequate power or sample sizes. Colonization is an easier metric to measure than actual infections. There was discussion regarding whether the new guideline should be consistent with the original one and whether it used only infections, or also colonization, for the outcomes.

Ms. Stone said that the original guideline used all infection outcomes. Mr. Hageman agreed and added that the prior guideline looked reviewed existing data and any outcomes. The current system of identifying critical outcomes was not in place, as this guideline was grandfathered in. The prior methods were not as systematic as the current methods. The public comments for this issue resulted not in GRADE evidence, but in a systematic review.

The reason for separating the products was related to the timing of their development. The sponge was developed first, so more data were available about it. Regarding a rationale for combining the products, they are similar concepts for a local antiseptic. Unless there is a technology that is broadly different, they can be combined. It is not clear whether that rationale can be translated to other areas effectively.

Consumer's Union asked about CHG resistance and whether it needs future examination by HICPAC. Ms. Stone said that CHG resistance is an outcome of interest. It will be summarized as such in the GRADE tables; however, there is a paucity of evidence.

One of the challenges with CHG is agreeing on what constitutes resistance by in vitro testing. The underlying science and clinical microbiology needs to be determined.

It was noted that the Compendium addressed chlorhexidine bathing. It may be worthwhile to investigate the background behind that recommendation. Contributors to the Compendium recalled that the comment was not based on particular evidence. It is a theoretical concern to be factored in.

Some clinicians are concerned about obscuring the exit site of the catheter. Some dressings are opaque and could mask exit site infections, bleeding, or other complications and lead to delayed diagnosis.

Regarding resistance, it will be important to move the literature to report not just a percent of isolates obtained as a resistance profile. The population risk may have been reduced, and whatever remains may have proportional higher resistance, but the benefit may still be high. A meaningful clinical break point for resistance is not known. The dominant means in the literature for measuring resistance is not optimal.

Regarding how other organizations implement or make decisions in these areas, APIC members rely on the information that is released by HICPAC in these recommendations. Many APIC members do not have the opportunity to understand the process by which the decisions are made, so they are influenced by CDC and HICPAC guidelines shared by APIC. Vendors place pressure on APIC members based on the results of different trials. It is difficult for individuals to make those decisions.

The Public Health Agency of Canada (PHAC) deals with the same issues and does not have documents to address them. PHAC will assess the work of CDC and HICPAC closely.

AORN has faced these issues several times in creating guidelines. A few times, AORN states that the perioperative team may evaluate a certain emerging technology for use in the perioperative setting with the multidisciplinary team. In this case, the guideline lists the rationale that the evidence is conflicting and which evidence supports and which refutes. This information provides guidance and support to the teams that make decisions. AORN documents stand for five years, so there is room for the team to make decisions as new evidence becomes available.

HICPAC asked whether the questions should be considered in relation to CHG, or in general. Ms. Stone answered that general consideration would be helpful, as it would be useful to maintain the rationale established regarding CHG.

The decision to combine products into a class or to consider them together will be based on the amount of evidence available. It may not be possible to make a general statement about combining. It may be preferable to combine as many products as possible into a category, assuming that there is enough research comparing them. In the evidence table, there was one RCT for gel, and the rest were other applications. They may need to be considered separately, as there may not be enough data to combine them.

Regarding CHG, CSTE said that there may not be evidence regarding standard versus coated catheters.

As rates are driven lower and as there is better technology that brings options to reduce rates, time is very important. For instance, if a study from 1995 is quoted, it should be remembered that at that time the acceptable rates were high and the best practice was not in place. Even in studies conducted recently, there is no longer clear evidence of the additive benefit of certain products. Each product may demonstrate benefit to an acceptable core background of behavior. In terms of making a statement in the guidance that all of the products should therefore be implemented, HICPAC should be careful regarding what is recommended as "core." "Core" should refer to the best practice under every circumstance, no matter what else is added. If there have not been multiple head-to-head studies to show that there is always incremental

benefit in addition to other options, HICPAC should be careful in defining recommendations as IA. Many approaches may be effective, but they may not be necessary together. This issue makes study designs more challenging. In order to detect an incremental benefit on top of what is known to be effective, the size and the cost of the studies will be increasingly prohibitive.

HICPAC could incorporate that concept into the evaluation of the quality of the studies. The evaluation of studies on coated sutures encountered this challenge, as some trials were quite small or showed impressive reductions in extremely high starting rates that may not be a real-world setting for current rates or rates that are expected when all other best practices are in place. The evaluation could include additional criteria addressing whether the study controlled for best practices, the size of the trial, and the starting point of the rates and whether it is acceptable to demonstrate incremental benefit.

Regarding combining products, criteria are needed to allow products to be regarded as "similar enough." These criteria might be that they have the same active agent, the same site of action, the same mode of delivery, and the clinical trials that have examined their efficacy have utilized identical or at least very similar outcomes. An additional consideration could be the timespan of delivery, if it is relevant to the product. Another secondary criterion might be associated adverse events.

Dr. Bell thought the discussion had been helpful. A number of products are emerging, and various aspects of healthcare quality are affected by new technologies. He hoped not to struggle with a disheveled evidence base that does not yield good conclusions. There may be merit in laying out minimum standards for how evidence must be presented in order for a product to be considered. The span of work is untenable. There is a need for a recommendation, but the work must be able to be done.

Dr. Diekema agreed and noted that there are published standard approaches to evaluate these trials.

Using Data for Prevention: Targeted Assessment for Prevention (TAP)

Carolyn Gould, MD, MSCR
Division of Healthcare Quality Promotion
National Center for Emerging and Zoonotic Infectious Diseases
Centers for Disease Control and Prevention

Dr. Gould provided HICPAC with an update on how DHQP has been working with partners on using data for prevention, focusing on the Targeted Assessment for Prevention (TAP) strategy. NHSN data can be used for action in many ways. More data are available because of the mandates for Catheter-Associated Urinary Tract Infection (CAUTI)/CLABSI and *Clostridium difficile* infection (CDI), the infections on which the TAP strategy focuses. The TAP strategy can be used to target hospitals with the highest numbers of excess infections. DHQP has been partnering with many groups, including CMS Quality Innovation Network – Quality Improvement Organizations (QIN-QIOs) and the Hospital Engagement Networks (HENs) as well as state health departments and multiple other partners with access to NHSN data.

The TAP strategy addresses a complex issue, so the approach to addressing it is as simple as possible in order to be effective. The framework for quality improvement (QI) is a linear progression:

- ❑ Target facilities and specific units within them using the TAP report function that is available in NHSN.
- ❑ Assess gaps in infection prevention in the targeted facilities and units of interest.
- ❑ Prevent infections by implementing customized interventions to address those gaps.

The TAP strategy has a website that will include all tools that have been developed for TAP. There are links to NHSN technical documents for providing TAP reports and links to stories and newsletters from partners.

The metric that serves as the basis for the TAP report was developed by Dr. Minn Soe in the surveillance branch of DHQP. The metric is called Cumulative Attributable Difference (CAD). It is related to the Standardized Infection Ratio (SIR), but it is different because it is not a ratio.

$CAD = OBSERVED - (PREDICTED * SIR_{target})$

The target SIR can be chosen based on the goals of the group, state, organization, or national HHS reduction targets. The lower the target SIR, the larger the CAD, or excess number of infections. As a default, NHSN TAP reports use the HHS target SIRs, but there is an option to customize it. For instance, a system that has exceeded the national targets may wish to have different targets. CAD is operationalized as the number of prevented infections needed to reach the target SIR in a similar timespan under similar conditions. The metric is useful because it is related to the SIR and provides a concrete number to translate the SIR into a target.

The development of CAD was described in a recently-published paper in *Infection Control and Hospital Epidemiology* (*ICHE*). When Dr. Soe began developing the metric, he initially considered its efficiency in enabling DHQP to target hospitals to reach the HHS targets. He considered the impact on the 2013 national pooled mean CAUTI SIR, which was 1.057, and the number of hospitals needed to reach the national goal of .75. Of the 1500 hospitals with a positive CAD, which translates to an SIR above .75, preventing 10,040 infections at 243 hospitals (19% of the total) would enable achievement of the national CAUTI reduction goal. Using the CAD to target hospitals leads to better achievement of the national goal than using the SIR, which was closer to 800 hospitals. This exercise illustrates that CAD is a potentially efficient way to reach the national target if it is assumed that intervening with fewer hospitals is easier with limited resources. The other hospitals that still need prevention measures should not be ignored.

Since the initial development of the metric, additional benefits of the TAP strategy beyond reaching a target SIR have been described. The TAP strategy is a focused approach to prevention that helps hospitals focus initial efforts. Within targeted hospitals, excess HAIs can be mapped to the unit level. This mapping is not always possible with the SIR, as the SIR is not calculated if the denominator is too small. Many hospitals can therefore only assess facility-wide data, not unit-based data, and some units can remain undetected even if they have problems.

CAD is a concrete prevention goal that is linked to the SIR. The tools that have been developed for the entire strategy have helped DHQP work with partners to identify specific gaps in infection prevention through standardized assessments of targeted units. Implementation strategies can be customized to address specific gaps. Units and hospitals are very different from one another.

Several tools have been developed to help implement the TAP strategy. TAP reports pull data from various parts of NHSN into one report: Event data, data from the annual survey, device utilization data, and pathogen-level data. The following illustrates the tools:

TAP reports can be generated at the facility level and at the unit level. Within a system, the report can rank hospitals by the total facility CAD. ICU data are separated from non-ICU locations. The SIR is included in the TAP report to emphasize that the SIR should be used as well as the CAD, as the CAD is a ranking prioritization metric, not a comparative metric. This distinction is important because although the CAD is risk-adjusted, it is influenced by the size of the denominator and will therefore pull out hospitals with the largest burden, which often have the largest denominator. For this reason, the metric is only used for targeting.

Pathogen-level data presented includes the total number of pathogens reported for the events and the actual numbers by pathogen. The pathogen data is useful as a high-level snapshot of the pathogens that are reported for CAUTIs. This information was particularly important when yeast was part of the CAUTI definition, as a predominance of yeast might indicate a different type of prevention strategy. A predominance of a single pathogen might indicate an outbreak.

A TAP report can be run for any duration of time. It is recommended that the report include at least a quarter's worth of data so that there are enough events to be representative. The unit-level TAP report can rank locations within a facility by CAD. This presentation allows a facility to determine the units that drive the overall excess. Frequently, a limited number of units contribute the most excess infections. This information allows a facility to focus initial efforts on the units that have the most excess.

Facility Assessment Tools have also been created to support the TAP strategy. When units or facilities have been targeted, the assessment questionnaire can be administered to assess staff perceptions, awareness, and knowledge of practices related to prevention. The survey should be administered to multiple staff at different levels within the facility or unit. The responses and variability in them can be revealing. The CAUTI tool is complete, and tools for CRI and CLABSI are being piloted. Ultimately, an integrated tool will have all of the elements and as few questions as possible. Pilot data will be used to hone the questionnaires down to the questions that yield the most information. Feedback from partners has been helpful in this process.

The reliability of the CAUTI tool was analyzed using pilot data from a QIO partner that conducted the assessment in four targeted hospitals. The analysis included internal consistency, the distribution of scores, and differences by facility. The tool was found to be reliable and internally consistent. There were significant differences in the assessment by facility. The next step will be to compare the gap assessment data with outcome data to learn which domains and particular questions are most related to the outcomes. A database that accompanies the assessments allows their results to be summarized and scored.

Regarding prevention, the third step of the TAP strategy, a CAUTI Implementation Guide has been created. The guide is a menu by domains in the assessment that links to existing, publicly-

available resources for prevention. DHQP conducted an environmental scan to find these tools, many of which were created by the AHRQ-funded national Comprehensive Unit-based Safety Program (CUSP) project. Additionally, an implementation tool from ANA is referenced. The Implementation Guide pairs with the results of the assessment with the CAUTI Implementation Tool, which will allow facilities to identify and utilize appropriate prevention methods. Gaps identified by the tool can be addressed using resources from the guide.

DHQP piloted the TAP strategy in 2014 with seven participating QIOs. This process helped refine the TAP report format, narrow on CAUTI as the starting infection of interest, and refine the initial Facility Assessment Tool.

The TAP strategy is being implemented in several settings. In the contract for the 11th Scope of Work for the CMS QIN-QIOs, all 14 QIN-QIOs are implementing the TAP strategy for CAUTI prevention. They include over 1350 hospitals in the 11th Scope of Work. CDC is providing technical assistance. Ten of the QIN-QIOs representing 28 states are implementing the TAP Strategy for CDI Prevention, and some of them are interested in CLABSI. Many of the state health departments that are funded by the Epidemiology and Laboratory Capacity (ELC) cooperative agreement are implementing the TAP Strategy for prevention of specific HAIs as well as general infection control improvement. A collaboration is ongoing with the HRET of the AHA in which they will engage partners to improve infection control in acute care hospitals as part of their Ebola-funded work. They will use the TAP approach to target and engage facilities. DHQP is in discussions with CMS Survey and Certification and the Joint Commission regarding implementing a TAP strategy approach to use existing data to guide and focus infection control surveys. CDC has reached out to hospitals with high CADs to direct them to ongoing initiatives, including the QIN-QIOs and AHRQ-funded initiatives to prevent infections.

As of October 1, 2015, more than 20,000 TAP reports have been run in NHSN by individual facilities and group users. This uptake is exciting. Users may not utilize the analysis function of NHSN because the idea of running reports may be intimidating. DHQP is considering developing a dashboard within NHSN to include TAP report data and other data on MDR organisms.

Qualitative feedback has been received from some of the QIN-QIO partners. The feedback has called the TAP strategy a game changer that allows for providing targeted information to the units that need it the most. Comments also note that the strategy is simple and elegant, which is a boon for infection preventionists.

DHQP has developed a TAP Strategy "How To Guide" in response to user requests for a step-by-step guide. There is a guide for a group user and for a facility user. The guide includes examples from QIN-QIO partners who have been using data in different ways. One user creates graphical representations of the TAP reports. The figures are useful for reporting to hospital administration and for making a case for addressing issues with and within facilities.

Discussion Points

Dr. Cardo said that TAP helps facilities that do not know how to begin, because it provides tools for making a concrete, first step to address targeted problems. It also provides concrete information that clinicians, administrators, and others can understand. The flexibility of the strategy is important as well. CDC's role is to provide measurement tools to help facilities determine their directions in infection prevention as well as implementation tools. The strategy continues to improve over time as it is adopted by partners and as it evolves based on feedback. She asked for HICPAC's feedback regarding how institutions use data for prevention, and how to motivate people to use the TAP strategy. As data are examined more thoroughly, more ways to prevent infections and show progress are identified. DHQP would appreciate ideas regarding how to engage more infection preventionists, healthcare epidemiologists, and others not just to collect data, but to use it.

HICPAC agreed that the TAP tools will be powerful for QI. CAD is volume-driven, which raises concerns about ranking hospitals. Because of volume, certain facilities that perform more of certain procedures may be ranked low even if their performance is not worse than other facilities. CAD is useful for internal QI, but it should not be over-interpreted.

Dr. Gould agreed that the goal of CAD is for it to serve for internal QI purposes, not as a comparative metric. The "how-to" guide explains this point, and the division is working on other communication and messaging to reinforce that CAD is for QI and that the SIR should still be used for comparative and reporting purposes.

It has been exciting for HICPAC to see this effort evolve over time. HICPAC asked if the assessment tool is available on the website to be accessed by facilities that are not in NHSN, whether the assessment questionnaire is administered to front-line workers to learn about their opinions and practices, the timeline for the availability of the "how-to" guide.

Dr. Gould responded that the assessment tools are not on the web, as they are still undergoing revision. The CAUTI tool has been piloted and revised and can be shared. When the tools are combined into one tool, it can be shared. Regarding who is assessed in the questionnaire, DHQP recommends that facilities conduct on-site assessments with various staff members. Many facilities found value in the real-time teaching moments that cues to action that emerged. Some facilities conducted group interviews, and some distributed the tool to staff remotely. Remote distribution misses the opportunity for delving more deeply, teaching moments, and discussions. Nevertheless, it is still valuable. DHQP has not thus far recommended a specific number of healthcare personnel to be interviewed. DHQP has emphasized that the assessment should include personnel at different levels, from front-line nursing staff to institution leadership,

in order to yield a good representation of knowledge, awareness, and perceptions. The "how-to" guide is in the final stages of completion and should be available soon.

CSTE commented on the usefulness of the TAP strategy, especially as it provides concrete information. In 2013, the Tennessee state SIR was 1.38. Five hospitals comprised 50% of the excess infections. If those five facilities reached the HHS goal of 0.75, the state SIR would decrease to 1.0. If the five facilities with the highest SIRs eliminated every infection, then the state SIR would decrease to 1.17. This example illustrates the power of targeting resources. Regarding ranking, after discussions with the multidisciplinary advisory group, the state of Tennessee sent facilities a quarterly progress report card that showed the number of observed infections, the number of expected infections, their SIR, their CAD, and the state's SIR at the time. The report card also had a column that said: "Are you in the top five hospitals in the number of preventable infections in the state of Tennessee?" Facilities were thereby put on notice that they were major drivers for the state. That information is not a true ranking, but it has been powerful in engaging hospital leadership. The hospitals with excess infections are not always the largest-volume hospitals

From a public health standpoint, it makes sense to target larger hospitals that have higher-than-average SIRs. Because they care for more patients, they have more events and more ownership and obligation to ensure that they are operating at least at the standard of care. The TAP strategy can illustrate other important issues as well. Large facilities tend to be open to finding new ways to reduce infection, and involving their leadership is beneficial. If the assessment shows no process problems, then the institution may lack critical adjusters and find opportunities to rethink measures for certain high-risk groups. A great deal of research shows that if low-volume hospitals that are not included in CAD are lumped as a group, they uniformly have higher surgical site infection (SSI) rates than larger-volume hospitals. This example shows CDC that when the CAD is applied, there should be a lumping check to determine whether there might be a driver of low-volume, poor care that will not be discerned in this metric. If this dichotomy exists, effort should be applied on the population level for small, lower-volume hospitals in addition to the attempts to reduce the numbers of infections.

The State of California has targeted hospitals using a "data for action" strategy using CLABSI rates on the unit level. The state invites hospitals to receive an expert assessment visit if they are targeted in the public report. Because there is a lag in the publication of data, the TAP report has helped the state because it allows the state to conduct interim assessments. It would be interesting to work with the HAI advisory committee about the TAP report and to create a statewide strategy for the use of the report. The role of the state health department could be to ensure hospitals understand how to use the report for internal QI.

The premise of focusing limited resources on a smaller number of hospitals has merit, but HICPAC cautioned that they are more likely to be larger hospitals with more complex environments. The approach might divert resources to where they might not be as fruitful, as they may already have systems in place. Working with an increased number of smaller facilities may have a greater cumulative effect. CAD provides tools for units so that they may set their own goals and track their own progress toward them.

HICPAC encouraged DHQP to consider visualization and how the TAP report information is presented because the data should be used to affect change. Pie charts may misrepresent information. There are tools and literature available on how people best process information and act on it.

Dr. Gould agreed that different learners will understand information in different ways. It is important that any presentation of data will not be misinterpreted.

APIC looks to partner and provide additional education regarding the implementation of TAP reports and how to use the information for infection preventionists at the front line. The tool is as useful for those professionals as it is for state agencies and QIOs.

Infection preventionists in smaller facilities in multi-hospital systems may not necessarily be comfortable in the analytic realm of NHSN. The idea of a dashboard to present data is potentially helpful.

SCCM said that the information in the TAP report is potentially compelling. There is some hesitation, however, because it will never prioritize improving small rural hospitals where HAIs have impact.

HICPAC asked whether the 0.75 goal is based on knowledge of where the average is now, or on newer data indicating the state of the nation. Dr. Gould replied that the goal is based on the original 2013 HHS goals. The updates are still in the clearance process.

The 2015 SIRs for CAUTI will use the old baseline. DHQP will create tools for facilities to use to recalculate their data until 2016, when 2015 will be the new baseline for the SIRs. Because of new definitions for CAUTI, the 2015 SIRs will be lower. There are ways to adjust the data to account for the definition changes until the new baseline is established. The CAUTI SIRs were decreasing at the end of 2014.

The California Department of Health does not have access to the same data as the QIN that it works with; because it is not in the state law, the department does not have access to CAUTI data. There was discussion regarding the data use agreement for NHSN that would make the data more readily available to the HAI programs that are funded by CDC. This change would require changing the agreement with the hospitals.

Dr. Bell said that there is strength in influencing policy. While focusing on a range of healthcare locations, DHQP wants to be useful for policy solutions. It is worth considering a next generation tool or analytic component that would be useful, based on state experience.

HICPAC asked if the assessment tool for CAUTI includes questions about culturing practices, microbiology laboratory practices, and similar factors. Dr. Gould answered that laboratory practices are not included in the CAUTI tool, but it is open for revision. The tool asks about culturing practices of asymptomatic patients. There are laboratory questions on the CDI tool in terms of stool rejection policies.

One of the primary strategies of hospitals is to perform as few cultures as possible, using a variety of approaches such as laboratory-focused reflex testing.

The VA has particularly been looking at CDI using the SIR, CAD, and TAP report. The VA decided to focus on the TAP and called the top five facilities. If the phone call was not effective, then the team conducted a site visit. The hospitals tended to be larger facilities with expertise, not small facilities with less expertise. They did not have verification processes in place to

confirm that they are doing what they say they are doing. A lack of knowledge is not the problem. The problem is a lack of consistency.

Dr. Gould said that the approach of individual assessment of practices of front-line providers came about because when facilities are asked about policies and procedures, little information is gleaned. The survey is the next best thing short of direct observation of care.

Update on HICPAC Workgroup for Endoscope Reprocessing

Jeff Hageman
Division of Healthcare Quality and Promotion
National Center for Emerging and Zoonotic Infectious Diseases
Centers for Disease Control and Prevention
Designated Federal Official, Healthcare Infection Control Practices Advisory Committee

Mr. Hageman thanked HICPAC members Vickie Brown and Lisa Maragakis for volunteering to assist. He explained that workgroups are created to provide information or advice federal advisory committees. Their activities may include gathering information, analyzing relevant issues and facts, and drafting proposed recommendations for deliberation by HICPAC at a public meeting. Workgroups do not provide advice to CDC or HHS; rather, they work with issues, generate strategies and options, and review information between HICPAC meetings, given that there is not enough time to discuss all issues in-depth at the in-person meetings. The workgroups report to the full HICPAC to inform HICPAC's deliberations and overall recommendations to CDC. Workgroups must include at least two HICPAC members. They represent an opportunity to involve external experts with unique perspective or knowledge into the process. Non-federal consultants are required to complete conflict of interest disclosure statements before they participate in the workgroup.

During the July 2015 meeting, CDC asked HICPAC to provide input on recommendations and strategies to improve facility practices for endoscope device reprocessing. There needs to be innovation and improvement of the devices themselves, but in the interim, the challenges of training staff and improving the reprocessing processes must be addressed. HICPAC is forming a workgroup that will include HICPAC members and liaisons as well as experts in device reprocessing to develop draft strategies to improve these practices for HICPAC to consider. The target audience for the recommendations will be hospital infection prevention and control programs or other facility-level programs to improve practices. Separate work is ongoing with other federal agencies. For instance, FDA has advisory committees considering improvement of the device processes.

The workgroup is in progress and includes representation from organizations that are not represented on HICPAC, such as AAMI, the American Gastroenterological Association (AGA), and the International Association for Healthcare Central Service Material Management (IAHCSMM), which conducts accreditation of some reprocessing staff. The workgroup also includes representation from other federal agencies that address related issues, including FDA and CMS. Representatives from these organizations are being identified and their conflict of interest forms are being collected.

The workgroup will consider strategies in several areas:

- ❑ The most important areas for reprocessing in a facility and how to identify all of the areas across a facility or system where reprocessing occurs; there is a wide variety of staff as well as locations involved in reprocessing
- ❑ Ways to standardize training and assessment of competency of the healthcare personnel involved in reprocessing
- ❑ Effective ways to engage manufacturers in the process for training and education
- ❑ Considerations for audit and periodic reassessment of procedures
- ❑ Supplemental measures, given concerns regarding the increase in use of microbiologic culturing and an uptick of double-reprocessing and repeat high-level disinfection (HLD) in the absence of culturing
- ❑ Centralization of HLD or oversight within the healthcare facility: who owns this process and who should be involved in reprocessing decisions for the healthcare setting and system?

The workgroup could also address issues discussed by HICPAC in this meeting. Regarding endoscopes in particular, the workgroup could consider factors to improve cleanability. The workgroup could cover other strategies and guidance from which facilities could benefit. HICPAC liaison organizations can provide insight into their activities in this area, such as reprocessing guidelines that are currently in development, in existence, or out for public comment, as AORN does. Liaison organizations may have guidance, recommendations, tools, and education efforts that the workgroup should consider in its work. HICPAC was invited to provide feedback on the general focus areas for the workgroup and on additional topics that should be covered. The workgroup needs a clear charge so that it can meet the timeline of presenting draft strategies for review at the HICPAC meeting in March 2016.

Discussion Points

Dr. Maragakis added that there are many aspects to this work. Regarding medical devices in general, the workgroup might consider working with a facility's value analysis committee or setting up a mechanism in facilities to review new equipment before it is installed and to review the cleaning and sterilization guidance. The workgroup can provide guidance for facilities regarding the procedures and checks that can be in place before devices are introduced.

Ms. Brown agreed and hoped that the workgroup will be able to develop a guidance document that can help support the infection preventionists who may not have robust resources to delve into training and documents. It takes a great deal of support to provide the information that infection preventionists with limited access to a hospital epidemiologist may have to accomplish the same thing.

DNV Healthcare asked whether the document will address the size of the room in which processing takes place. Every hospital has a different area for processing, and some are so small that there is risk of recontamination. HICPAC suggested that a concise summary of available guidance about physical space requirements could be included.

Although the workgroup will focus on reprocessing duodenoscopes, it is helpful that the document will also highlight general principles that are important for reprocessing across the board.

APIC asked whether the workgroup will also consider manufacturers and the inherent challenges associated with accommodating products that are difficult to clean. Regarding value analysis, these programs in robust organizations have not historically considered the cleanability of items. It is important to emphasize that the decision-making process should include that element.

HICPAC commented on efforts to centralize sterilization across medical centers, which have worked well. Reprocessing, however, is a different and difficult area. The example was provided of an institution that commissioned a Reprocessing Oversight Committee to oversee how to ensure competencies, track compliance, and evaluate new products.

PHAC has a 2011 guideline on this topic. They have begun to receive questions about reprocessing, especially when the reports of outbreaks surfaced. The PHAC Infection Prevention and Control Expert Working Group has recommended a literature review. Additionally, a survey protocol is being written to conduct a survey of gastroenterologists. The survey will compare a number of aspects, including settings in acute care hospitals and outside. PHAC is drafting a notice to respond to the questions indicating that the agency is reviewing the issue and will make new recommendations if necessary. PHAC does not have as direct a relationship with industry as CDC does. If possible with the HICPAC workgroup timeline, it would be ideal for PHAC to work alongside the workgroup. Dr. Diekema agreed that the HICPAC workgroup and PHAC should work together and add the PHAC representative to the workgroup.

APIC has released talking points and frequently asked questions (FAQs) on the issue for consumers and has submitted comments to the FDA.

SHEA is involved with the AORN guidelines.

Public Comment

Dr. Diekema opened the public comment period at 4:04 pm.

Renee Odehnal
Manager of Professional Education
Ethcon Biopatch Products

Ms. Odehnal offered comments on the HICPAC CHG dressing discussion. There are many facets to consider when evaluating CHG dressings. Foremost among those facets is the dressing's ability to reduce catheter-related bloodstream infections (CBIs), which is dependent upon the dressing's active ingredient and ability to deliver it to the skin. When the previous guidelines were created, essentially one sponge and one gel were available. The products have continued to generate discussion, including comparing their cleared indications as well as the quality of evidence of each. In addition, and perhaps adding to confusion for healthcare providers, various other dressings have come to the market, including CGI film dressings and several more sponge dressings in which CHG has been added as a preservative to prevent bacterial growth within the dressing; the dressing lacks the ability to deliver CHG to the skin, and there is no clear indication that the product has been proven to reduce CBI. Clinicians are not always equipped to analyze these differences, thinking that "a sponge is a sponge," or "it's got CHG in it, it must do the same thing." Vendors can share information and educate, but bias

limits their credibility. In addition to strong evidence-based guidelines, clinicians would benefit from guidance regarding evidence-based product selection.

Rachel Stricof
CSTE Consultant

Ms. Stricof hoped that as the endoscope guidance is developed, the workgroup would keep in mind the full array of settings in which these procedures are being performed, who is responsible for oversight in these settings, and who is responsible for performing these duties. There have been discussions regarding human factors and engineering. The Multisociety Guidelines are a fine guidance for people who know what they are doing, but in the majority of institutions where there are problems, the person responsible for reprocessing speaks English as a second language and does not read the instructions thoroughly. Even if they did, the guidelines require over 40 steps. It is beyond the capability of most people to reprocess correctly and to do it correctly every time. Another set of guidelines may not necessarily get the field where it needs to be. Reengineering the design of the products themselves and establishing standards for the individuals who are responsible for various duties would be beneficial. When the guidance is written, the workgroup should keep in mind who will read it. In the majority of offices, no one has seen the Multisociety Guidelines, the Society of Gastroenterology Nurses and Associates (SGNA) guidelines, or the American Society for Gastrointestinal Endoscopy (ASGE) guidelines. The workgroup has a monumental task ahead of it.

Discussion Points

HICPAC noted that the automotive industry has lessons to teach regarding how to make certain technologies safe with process. Ultimately, better design must be implemented.

The reprocessing workgroup will address issues related to delivering training and information to the multiple people and disciplines that may be responsible for reprocessing devices. This area is where the disconnect exists. The technology will improve, but it will take time. In the meantime, the point is well-taken that there is a knowledge deficit regarding how to get correct information to the right people so that they can understand it.

Dr. Bell noted that the HICPAC workgroup does not include representatives from the world of materials management. He wondered if HICPAC liaisons could help reach out to those groups and other important implementer groups to participate on the workgroup and bring the real-world perspective to their proceedings.

APIC noted that IAHCSMM is the organization that represents sterile processing personnel and could be a key partner.

Recognition of Retiring Members

Dr. Bell recognized two HICPAC members who were rotating off of the committee:

- ❑ Dr. Susan Huang
- ❑ Ms. Gina Pugliese

He thanked them for contributing their insights and skills to HICPAC and looked forward to their continued involvement in HICPAC activities. Mr. Hageman presented Dr. Huang and Ms. Pugliese with a certificate and a letter of appreciation from Dr. Tom Frieden, CDC Director.

Liaison / *Ex Officio* Reports

ACOEM
ACOEM is rewriting the guidance for occupational health services in medical centers. It is a practical document with many hyperlinks, many of them to CDC sites. Its intent is to provide guidance to occupational medicine practitioners in hospitals regarding not only infectious hazards, but also chemical, physical, and psychosocial shift-work based hazards.

America's Essential Hospitals (AEH)
During Sepsis Awareness Month, AEH hosted a "Reducing Sepsis, Saving Lives" webinar that highlighted the work of two hospital members who have reduced sepsis shock and mortality. It also shared useful tools for addressing sepsis. AEH works by connecting hospitals to one another. In June 2015, AEH concluded its formal engagement with its member hospitals as a HEN and provided those hospitals with a CAUTI, CLABSI, and SSI data report stratified by age and gender to help hospitals identify potential disparities in care, which is a focus of AEH's mission. The group signed on to the foundational principles of the US Stakeholder Forum on Antimicrobial Resistance (S-FAR), convened by IDSA. AEH also took part in International Infection Prevention Week. Using its network, AEH disseminated targeted communications to members with social media, the website, and other means to draw attention to International Infection Prevention Week resources and materials, including healthcare professional pledges designed to be a public display of advocacy for infection prevention as well as hand hygiene and other materials.

National Association of County and City Health Officials (NACCHO)
NACCHO shares information with local health departments that is invaluable for responding to HAIs. Three health departments are participating in the NACCHO HAI Demonstration Site Projects: the Florida Department of Health; DePage County Health Department in Wheaton, Illinois; and the Philadelphia Department of Health in Philadelphia, Pennsylvania. The departments have worked together to develop tools for antibiotic stewardship and collaborated on how to implement them in their jurisdictions. The sites have found common barriers and hope to develop an HAI guidance document for local health departments to engage in HAI prevention activities. NACCHO works with several of the HICPAC liaison associations and hopes to continue to do so.

SHEA
The SHEA spring conference will be held May 18-21, 2016, in Atlanta, Georgia. It will be co-chaired by Drs. Sylvia Muñoz-Price and Tom Talbot. SHEA hopes to expand its in-depth scientific program further while appealing to a broad audience of infection control practitioners as well as healthcare epidemiologists and epidemiologists-in-training. This year's conference will have three different certificate programs: the standard SHEA basic training program, programs in infection control and prevention in long-term care facilities, and a new program in antibiotic stewardship. Other education developments within SHEA include the primer in healthcare epidemiology and infection control, an online program that is offered to a wide range of audiences, including infectious disease fellows and infectious disease practitioners. It launched on June 1, 2015. To date, there have been over 250 registered participants. Regarding guidelines and expert papers, SHEA contributed five comments to the Choosing

Wisely campaign. Two of the comments focused on infection control principles regarding devices and reducing unnecessary testing from a microbiological perspective; three comments focused on antibiotic utilization and reduction of unnecessary antibiotic use. Additionally, SHEA has an active guidelines committee. Over the last two years, guidance documents have been issued on animals in healthcare facilities and infection prevention for visitors to healthcare settings. Guidance documents in development focus on the duration of contact precautions, initiation of antibiotics in long-term care facilities, and infection prevention in anesthesia, SHEA has been involved with the endoscope and HAI programs. SHEA submitted comments through a workgroup to FDA in their public meeting, and some SHEA experts provide guidance to FDA on an ongoing basis. SHEA has been involved with the CMS reform requirements for long-term care facilities, having submitted several comments focusing on the organization of infection control programs and antibiotic stewardship programs in long-term care facilities.

CSTE

The CSTE-CDC HAI Data Analysis and Presentation Standardization Toolkit has gone through the clearance process and is near publication and release. It was developed in response to a position statement of two years ago that was requested at a HICPAC meeting. The CSTE-CDC Antimicrobial Resistance Surveillance Taskforce will likely be launched in January 2016. Its earlier scope was limited, having only focused on CRE. In light of Ebola, its scope has been broadened for the new launch. The taskforce will likely include liaison positions with professional societies such as SHEA and APIC. CSTE and CDC are working on a Reportable Conditions Knowledge Management System, a real-time portal to enhance disease surveillance by providing comprehensive information to reporters regarding what is reportable, when, and why. It will serve as a "one-stop shop" for case reporting and for electronic laboratory result reporting. Discussions are underway to create a council, with a name still to be determined, to improve HAI outbreak response. It will be modeled to a similar council that improves foodborne outbreak response. The governance and bylaws for the council are being structured, and other organizations will likely participate in it. The CSTE HAI subcommittee is forming a working group on getting requirements for an extensively drug resistant organism (XDRO) registry similar to one created by the state of Illinois. The registry would use existing infrastructure, such as communicable disease surveillance reporting and electronic laboratory result reporting. Interested parties from other organizations are welcome to participate. CSTE contributed comments to the *Federal Register* on the proposed CMS rules for the Reform of Requirements for Long-Term Care Facilities and regarding the end-stage renal disease prospective payment system and quality incentive program.

AORN

AORN's comprehensive guidelines for flexible endoscopes are available for public comment on the AORN website through November 22, 2015. AORN has been conducting guideline implementation workshops, a new approach to reach staff nurses at the bedside. The workshops have been held in six different cities in collaboration with industry partners. The last one will be held in Atlanta, Georgia. The workshops include a lecture on the guidelines and a hands-on session with vendors to allow nurses to interact with products and to receive practical guidance on implementation. Because of generous support from industry partners, a free subscription to the e-book is available to participants. AORN looks forward to continuing the workshops in different topic areas. AORN is beginning work on guidelines for hand hygiene in the perioperative setting. It will be limited to studies in the perioperative setting and will have surgical hand scrubs as a main focus. Another new guideline will focus on the management of surgical smoke. Guidance regarding surgical smoke will be gathered from the AORN guidelines

for electrosurgery, laser safety, and minimally invasive surgery. AORN has an exciting new industry partnership to offer a surgical smoke certification program.

SIS

SIS is nearing the end of reformulating guidelines for the management of intraabdominal infections. They will be published within six to eight months. In parallel, IDSA is working on guidelines for intraabdominal infection. SIS is involved with that working group. The two guidelines will be complementary not competitive. The SIS guidelines focus on surgical technique, where the IDSA guideline emphasizes bacteriology, resistance, and other issues. With help from DHQP staff, SIS was able to host CDC representatives at its council meeting in Chicago, Illinois, in October 2015. The meeting included discussion regarding how SIS can partner with CDC. Two related projects were identified: how SIS can help build a curriculum for quality and safety officers who need to understand infectious disease and surgical infectious diseases and infections, such as CLABSI and CAUTI. Multiple members of SIS are interested in the concept of patient-gathered information, specifically in SSI, such as photography of wounds and image capture to feed into a post-discharge surveillance activity. This concept harnesses new technology and is exciting.

PHAC

PHAC is working on a number of guidelines. The guideline development process is being reviewed across the agency. A number of groups within PHAC develop guidelines in a range of areas. The review process will continue for the next six months. Canada held recent national elections. There was slower communication during the elections, so some guidelines were slightly delayed. Regarding emerging pathogens, PHAC is making small updates to the posted MERS-CoV guideline. There are no major changes to the recommendation; however, PHAC is considering the management of healthcare workers and patients exposed to a confirmed case as well as the management of asymptomatic healthcare workers and patients who are polymerase chain reaction (PCR)-confirmed for MERS-CoV. Several surveillance documents are available or are in development. A document on AMR organism surveillance from 2009-2014 was recently released. Regarding Ebola, a document will be released soon on infection prevention and control measures for pre-hospital care and ground transportation of patients with suspected or confirmed Ebola. The impetus for this document was the identification of gaps for medical first responders and paramedics. Core guidelines under development include the guideline on the prevention of transmission of bloodborne pathogens or viruses from infected healthcare workers to patients and the infection prevention and control guideline for personal services, such as tattooing and body piercing. Several guidelines have been developed for update: an update on the prevention and control of occupational infections in healthcare and an update on dialysis.

APIC

Infection Prevention Week in October 2015 was successful. APIC is partnering with AHA on their United Against Flu campaign. APIC has launched a new platform for its online text to make it more readable and to add navigation features. The CLABSI Implementation Guide is anticipated for release in November 2015. Additionally, a Long-Term Care Unit Guide will be released. This work came as a result of a grant from HRET. The *Prevention Strategist* Fall 2015 issue focused on many topics that are in the news, including the large listeria outbreak and the White House Forum on Antibiotic Stewardship. The Winter issue will focus on CHG and endoscope reprocessing crosswalks. APIC has completed its mega-survey on the state of the infection prevention profession. There was a high return rate from the survey, so APIC will be able to share information about demographics, organizational structure, competencies,

certification, and compensation for infection preventionists. The research committee will release an executive summary in 2016.

ASTHO
ASTHO has a number of ongoing activities related to monitoring HAI-related policies and initiatives, as well as legislative tracking. ASTHO is finalizing a web-based toolkit to support health departments as they work to access electronic health records (EHRs) for healthcare-associated outbreak assessments. This effort is based on an assessment of experiences and tools from 12 different states. ASTHO supports state health agencies as they conduct Ebola and infection control assessments through the federal ELC supplemental funding. Key activities include convening state team meetings to explore lessons learned, assembling an HAI outbreak response council, launching a website to share infection control and outbreak information and resources, developing and testing public health communications tools, and facilitating a workshop to refine roles and responsibilities and enhance coordination during outbreak responses.

Consumer's Union
Consumer's Union continues to work on AR issues. At the first National Action Plan for Combating Antibiotic-Resistant Bacteria (CARB) meeting, Consumer's Union commented that patients are missing from the plan; Consumer's Union is calling for the plan to require hospitals to notify patients when outbreaks occur. Further, the plan should require hospitals to notify public health authorities when outbreaks occur. Two of the series of three articles on AR in *Consumer Reports* have been published. The third, which focuses on antibiotic use in farm animals, will be released on November 18, 2015 and in the January 2016 issue of the magazine. Consumer's Union conducted a successful experiment after the last ratings were complete. The dozen hospitals with the poorest scores on Methicillin-resistant *Staphylococcus aureus* (MRSA), CDI, and a composite infection score were contacted. Consumer's Union asked the hospitals for comment on their scores and about their plans to address them. Responses were received from several of the hospitals. Consumer's Union conducted a social media campaign about "the low-down dozen." The campaign was successful in securing commitment from the hospitals to engage in more activities to prevent infections. After two weeks of social media in their communities, all of the hospitals had responded to the questions. Their answers are posted on the Consumer's Union website. This effort is related to DHQP's TAP work, as the TAP approach is internal and passive. Consumer's Union believes that if the public is not involved in these efforts, hospitals will not act. Work on infection prevention issues has gone on for decades, and it should speed up. The work is challenging for many hospitals, but calling the community's attention to the ratings and how hospitals are progressing or not progressing is an important part of stimulating change. Consumer's Union will continue doing social media outreach in different ways and with different focus areas.

IDSA
IDSA remains active on a number of fronts related to infection prevention. Antibiotic stewardship and judicious use are a focus in a number of domains. Regarding implementation, S-FAR is an important initiative, and IDSA works with all partner organizations to develop improved implementation strategies and actions for the CARB plan. The focus is not only on human health, but also on animal health and agricultural uses. IDSA has active engagement in the proposed long-term care rule and opportunities to protect patients across the spectrum of care. Regarding education, the 2015 ID Week was successful. Educational offerings continue with IDSA partner societies and groups. IDSA maintains a robust list of infection prevention and stewardship-related practice guidelines. In the legislative realm, IDSA remains active in

targeting not only policies regarding stewardship implementation, but also in the Reinvigorating Antibiotic and Diagnostic Innovation (READI) Act, which is important because it highlights the vital connection between diagnostics and therapeutics regarding judicious antibiotic use. IDSA continues to engage the public at large regarding awareness of issues associated with antibiotic stewardship.

SCCM
SCCM's national meeting in February 2016 will include several sessions on antimicrobial resistance and stewardship in the critical care setting. Regarding sepsis, a study published in 2015 showed that fewer than half of Americans could identify sepsis as a disease, despite the fact that a similar number of people die of sepsis as die of heart attacks. SCCM was pleased that CDC Director Dr. Tom Frieden served as ambassador for World Sepsis Day in 2015. SCCM continues to support collaboratives on improving sepsis care outside the physical ICU, where a great deal of sepsis happens. SCCM is collaborating with the European Society of Intensive Care Medicine (ESCIM) and has completed a revision of the sepsis definitions, which are out for organizational approval and publication process. The revision is quite different from the 2001 consensus criteria. For instance, systemic inflammatory response syndrome is not included in the definitional criteria. The Surviving Sepsis guidelines are under revision.

Health Resources and Services Administration (HRSA)
No report.

FDA
Regarding isolation gowns, FDA posted a guidance document in June 2015 requiring all manufacturers of the gowns that make Level 3 and Level 4 claims of performance to come into the agency for review for clearance. The comment period ended at the end of September 2015, and the manufacturers will be required to obtain clearance in the near future. They will not be allowed to market to anyone without that clearance. There will be a brief period in which marketing is allowed before the products are pulled to await clearance. Regarding duodenoscopes, the agency is actively working with the manufacturers of scopes as well as the manufacturers of sterilizing, reprocessing, and cleaning devices to determine whether the design of the devices allows for them to be cleaned as claimed. FDA is conducting its own testing to determine whether the devices are safe and effective, and whether there are problems with the design.

CMS
The CMS nursing home regulations have been released, and the infection control regulations are quite different from previous iterations. The Survey and Certification Group generally issues interpretive guidance of the broad regulatory language. The guidance gives facilities an idea of what will be required for compliance. Surveyors are also trained to assess compliance. CMS works closely with CDC on this issue and on piloting related initiatives. Further, CMS has been working with the Medicare Learning Network (MLN), an electronic communication platform that can disseminate either targeted or widespread messages in the healthcare community. Traditionally, the E-News messages focus on technical Medicare issues. The network is interested in adding quality and clinical issues to the messages. On October 22, 2015, the MLN E-News released an announcement, "New Survey Processes for Duodenoscope, Endoscopes, and Reusable Medical Devices." The announcement came after the release of CDC's health advisory and the multiple media reports about the issue with the duodenoscope. CMS has also seen disturbing survey findings on this issue as well. The announcement includes a link to the CDC advisory and a message supporting the advisory and describing how CMS is involved in

the issue. The announcement also describes new survey processes in which surveyors ask facilities specifically whether they conduct Endoscopic retrograde cholangiopancreatography (ERCP) or use endoscopes. The surveyors ask for the hospitals policies and procedures as well as the manufacturer's instructions. Surveyors are required to observe a scope reprocessing to ensure that the reprocessing is performed according to the manufacturer's instructions. Another process is related to immediate use steam sterilization, which some facilities still use for routine sterilization. The announcement reiterates that immediate use steam sterilization is not for routine use for sterilizing reusable medical devices. Links are provided to a survey and documents that specifically address these issues, as well as hospital infection control worksheet with specific questions on device reprocessing. The surveyor training that CMS developed with CDC on infection control has been used to build educational products. Continuing education credits are available for these courses. The first course was on hand hygiene, and the most recent release includes new courses on environmental cleaning and injection safety. CDC is effective at communicating issues as they arise; these issues can be amplified with the MLN. Some of HICPAC's products may also be of use as educational products.

NIH

Since the last HICPAC meeting, NIH has continued efforts related to Ebola. No additional patients have been treated in the last year, but NIH follows the four patients who were treated. There have been some surprises that have added to knowledge about the natural history of the disease, both in patients who are seriously ill and in patients who are less ill. Providing care for these patients in the sophisticated environment of NIH's Clinical Studies Unit was a benefit. NIH continues to support the development of two candidate Ebola vaccines, and clinical trials are ongoing in West Africa. NIH continues its investigations into the ongoing transmission of Vancomycin-Resistant *Enterococcus faecium* (VRE) in its hospital. It may be possible, in a long-term longitudinal study, to contribute information regarding the healthcare-associated epidemiology of these organisms. NIH continues to study CRE following its cluster. No transmission has been detected in the facility since July 2012, but 23 new discrete isolates of CRE, all of which are genetically dissimilar from each other and from the outbreak isolate, have been discovered. Of the 23, 20 have the *Klebsiella pneumoniae* carbapenemase (KPC) gene. Whole-house surveillance for these isolates continues once a month. Surveillance is conducted once a week for every patient in the ICU and bone marrow transplant unit.

Society of Hospital Medicine (SHM)

Mr. Hageman presented the update from SHM, as the representative had a last-minute conflict and could not attend the meeting. SHM continues work with HRET on the prevention of CAUTI and CBI in hospital settings. Some of the CAUTI initiatives have expanded beyond hospitals to long-term care settings. SHM has continued work on antimicrobial stewardship. In addition to participating in the White House Forum in June 2015, SHM has committed to expand initiatives focused on education of their membership. In November 2015, SHM will launch a new campaign targeting its 14,000 members to improve antimicrobial use. The campaign will begin with a webinar launch on November 10, 2015. Additionally, SHM works with the Society for the Advancement of Blood Management (SABM) on an Anemia Prevention and Management Implementation Guides. SHM also works closely with the Choosing Wisely initiative and has published recommendations that guide hospitalists toward high-volume care in transfusion decision-making. Additionally, SHM has received funding to develop a QI initiative related to opioid medications SHM recently developed an implementation guide for reducing adverse drug events from opioids, and an online toolkit is in development. SHM has also developed an implementation guide for implementing a bundle for ICU delirium. It will be completed in mid-October 2016 and will be posted online.

Adjourn

Dr. Cardo recalled her presentation at the beginning of the day. She reminded everyone that CDC works with and through the HICPAC members, ex officio members, and liaisons. CDC and its federal partners provide funds to support initiatives of its partners; CDC also seeks new partnerships beyond funding to work together in different ways to improve the prevention of infections. She encouraged new initiatives and additional ways to work together.

With no additional comments or questions posed, Dr. Diekema adjourned the meeting for the day at 5:01 p.m.

Friday, November 6, 2015

The second day of the HICPAC meeting was called to order at 9:07 am. on Friday, November 6, 2015. Mr. Hageman called roll to establish quorum, HICPAC members restated their conflicts of interest, and he reminded those wishing to provide public comment to sign in.

Control of Antimicrobial Resistance Across Healthcare Settings

John A. Jernigan, MD, MS
Division of Healthcare Quality Promotion
Centers for Disease Control and Prevention

Dr. Jernigan reported that DHQP has been moving toward more regional coordination for preventing the emergence and dissemination of multidrug-resistant (MDR) organisms in communities. The issue has been addressed in *MMWR* Vitalsigns™. He reviewed the rationale and findings of the report, which serves as a vision-setting document, realizing that not all jurisdictions are equipped to implement the approach. He hoped to hear perspectives from HICPAC and the liaison representatives regarding how to bring the vision to fruition.

The traditional approach to controlling healthcare-associated multidrug-resistant organism (MDRO) dissemination has been to encourage hospitals to implement infection control policies, procedures, and interventions independently. This independent approach in which each facility is siloed does not account for the very important contribution of inter-facility spread of organisms in and between healthcare facilities through the movement of colonized and infected patients. A more regionally coordinated approach would recognize the importance of this spread. Individual facilities are components of an integrated and dynamic network that is connected via patient movement. What happens in one facility may affect what happens in its neighbors.

This concept is demonstrated thoroughly in the literature. One investigation of a new introduction of KPC in Illinois carefully traced how the organism was introduced and spread within the facility. A long-term acute care (LTAC) hospital was at the center of this event. Many patients came to the facility carrying the organism, and it was amplified and sent out to various facilities in the community. If there was awareness of this interrelation, then interventions could have been targeted in even one acute care facility to have a significant regional impact.

Another recently-published article on an investigation of *C. diff* burden in California combined administrative coding data for *C. diff* in acute care hospitals with data on patient transfers between facilities. Major clusters of groups of hospitals that are tightly connected in terms of patient-sharing are depicted. Some facilities are tightly linked even though they are located geographically far from each other. The investigation considered the burden of *C. diff* in hospitals and found that the burden was related to the number of facilities from which they received patients. The outcome in the hospitals is influenced by connection networks.

DHQP has been asking whether there is an advantage to using a regional approach to MDRO prevention. DHQP also wonders what would happen if health interventions to reduce MDRO transmission were based on: 1) better situational awareness among an overarching body such as a health department; that is, if timely information were available on the incidence of MDROs from all facilities in a network; and 2) understanding of how facilities within a region are connected to each other in terms of patient transfer.

The division estimated the impact through mathematical modeling, which was published in the August 2015 *MMWR*. The division developed two complementary agent-based models in partnership with the University of Utah, which developed a 10-facility based model parameterized using transfer data from the VA healthcare system; and with a group from Orange County, California, which used their 102-facility model parameterized using real epidemiological data. The model results are shown as follows:

The project simulated the spread of CRE among patients in acute care hospitals, LTAC hospitals, and free-standing nursing homes in communities. The project then compared what would happen after introduction of CRE into these facilities according to three different approaches:

- Common Approach: the best estimation of current infection control activity and its effectiveness
- Independent Efforts: certain facilities in the region took extra efforts to address the problem of transmission of the organisms independently of each other and not in coordination with each other or the health department
- Coordinated approach: the coordinated, augmented approach was based on regional situational awareness and was targeted and implemented to be more efficient and effective.

Although there is some variation in the results, they share a message. In the 10-facility model, the status quo approach would expect to lead to region-wide CRE prevalence of approximately 12% in a five-year period. With independent intervention, the prevalence decreases to approximately 8.6%, and with coordinated facility intervention, the prevalence decreases to 2.1%, which represents a 74% reduction in prevalence. The Orange County model had similar results, with the status quo resulting in 15% prevalence, the independent facility resulting in 14% prevalence, and a coordinated approach resulting in 8% prevalence in a 15-year period. The models vary somewhat in their assumptions regarding timely access to granular facility-level information and facility-level triggers, but both models indicate that coordinated prevention approaches assisted by public health agencies have the potential to more completely address the emergence and dissemination of MDROs in comparison to independent facility-based efforts.

DHQP has taken practical steps to inform health departments regarding what they might do in their regions. The division has used Medicare data to examine Medicare patient transfer patterns in acute and long-term facilities. This work can identify networks of facilities that might be epidemiologically linked and considered units of intervention, or at least related to one another and placed on alert if a facility in the group has an outbreak of an MDRO.

A convenience sample from Washington and Oregon was used because the states have relatively few hospitals and densely-populated areas that are close to state borders. These regions and networks may not follow political borders, so facilities should think about their partners in neighboring states for coordination. The analysis defined a network as sharing greater than 100 Medicare patients within 30 days of discharge. Hospitals that are tightly related might be put on alert if one of them has an outbreak of an MDRO, and the hospitals might anticipate receiving high-risk patients and screen or be aware of them.

The division also retrospectively studied data from a partner health department that investigated an outbreak of New Delhi metallo-β-lactamase (NDM)-containing CRE in a hospital in the region. The outbreak was investigated thoroughly at the time. The division used the data to determine what might have happened if the networking data had been available. In the status quo, the facility experiencing the outbreak would be visited and told to improve infection control and to prevent transmission within the hospital. If the investigation had been able to take into account social networking data for related facilities that share patients, 22 hospitals would have been involved. They could have been made aware of the outbreak and cautioned to be aware of patients that transferred from the affected facility to take appropriate precautions.

Of the 22 hospitals in the network, 9 received a patient known to be infected or colonized with the MDRO. Of the facilities, 5 had additional outbreaks related to the transmission, and 4 additional facilities that were not in the network as defined also received patients. If transfer information had been coordinated, the facilities would have been aware of the outbreak. Since the outbreak, NDM organisms have been identified in another four hospitals in the state. It is not known whether those organisms are related to the initial outbreak. Of the 21 hospitals that were affected by the outbreak, 81% could have been identified using this information coupled with information regarding transfer of known colonized patients. It could be presumed, therefore, that using this information prospectively could help with effective response and stem emergence of dissemination of new and important organisms that are introduced in a community. DHQP is currently working with an active outbreak in a state that asked for this analysis. One hospital is involved, but the state plans to increase surveillance hospitals that are tightly-connected to it and to enhance communication upon transfer of patients from the index facility.

Although the Medicare data are readily available, and most states have access to state inpatient databases that include every admission of every patient, not every health department is in a position to generate these diagrams of networks. Other approaches can use information to improve coordination. The state of Tennessee has mapped annual incidence rates of *Klebsiella spp*. cases by county of residence.

A map like the one that follows from Tennessee can help target prevention resources in a manner that makes more sense than assuming that every county in Tennessee is equally affected by an isolate. The top three population centers in Tennessee are indicated by red asterisks on the map. It is worth noting that the *Kebsiella* cases are not concentrated there.

The implementation of a public health coordinated approach to antimicrobial resistance requires situational awareness across healthcare networks. The right data need to be available in order to identify and target problems. NHSN data are potentially useful in this regard, using the MDRO and Antimicrobial Use and Resistance (AUR) modules as participation increases in them. Steps may be taken to enhance participation in the modules to collect the needed data.

When problems are identified and recognized, interventions should be implemented in a coordinated fashion. CDC is providing guidance to health departments and hospitals and supporting states through the ELC cooperative agreement. There must be partnerships in the region itself to coordinate this work among acute care facilities, long-term care facilities, LTAC facilities, nursing homes, public health, and other entities.

Discussion Points

NACCHO commented on outbreaks in Florida, when facilities were hesitant regarding the social network approach because they do not want to know. A challenge at the local level regards how to engage hospitals and nursing homes to create a social network diagram proactively and to illustrate convincingly how the data could be helpful in an outbreak situation. Further, the local level struggles with not having access to experts to answer some questions regarding MDROs and complex outbreaks.

Dr. Jernigan replied that one strategy may be to share the initial example. These diagrams can be created without data from the hospitals themselves other than administrative sets that are already available. The facilities can be approached with the information regarding transfer links to other facilities and asked if they would like to be aware if a high-risk patient is coming to the facility from another facility in the midst of an outbreak. A hospital is likely to be interested in this information to avoid having NDM-CRE in the facility. He acknowledged that every health department does not have the expertise to do this diagramming. DHQP is trying to provide better resources to health departments. To the extent possible, DHQP can potentially provide support to health departments on an as-needed basis using at least Medicare data to create network diagrams. It is hoped that in the future, every health department will have the ability to perform this work.

HICPAC felt that this approach is a good direction toward understanding where these networks come from. The network diagrams are an important public health tool. To the extent that outbreaks are primarily known to public health and not to all facilities in a region, they are a good place to identify where to react first. It is important to note that patients often do not transfer directly from facility-to-facility, as they often go home or to another place before they are re-admitted. Direct transfers only account for approximately 10% of the patients that are shared in Orange County, California, for instance. The rates are slightly higher for LTAC facilities and nursing homes, but the links are not as tight as previously thought. Using networks to understand how facilities are most closely aligned, and being able to ask in the setting of an outbreak whether patients were in those facilities in the recent past, not just the direct transfer past, may be important. It would be instructive for the reports to be updated on a regular basis.

HICPAC asked for more information about the available data sources and a vision for data beyond Medicare that could inform this work. The tool is potentially powerful within a facility to understand unit-to-unit transfers as well.

Dr. Jernigan agreed that intra-facility movement is important to consider. DHQP uses the Medicare data in part because it is convenient and offers access to the universal population of Medicare recipients and every inpatient experience that they have. It also represents the highest-risk population. It will be critically important to compare the network analyses created based on Medicare-only data with analyses using all-payer data to determine whether the Medicare data is a good surrogate. Many states are using state inpatient databases, which have the same data, except for all payers within the state. There may be issues across state borders.

Almost all states collect a mandatory hospitalization line item data set that includes administrative data as well as a facility identifier. Many states have an encrypted identifier that is retained at the state level. This code can be used to track patients through the system. Some groups that do not have Social Security Numbers (SSNs), such as newborns, cannot be tracked this way. Patients are otherwise fully trackable. The states that do not use encrypted identifiers house information at the state level. These states could generate the nodal networks from that data. It is complicated to link this information to the Minimum Data Set (MDS), which requires nursing homes that receive Medicare to report on all of their residents.

It would be helpful to provide guidance to states stating the Medicare data set that is used and how to go about using it. The guidance could also describe other administrative data maintained by the state so that state health departments can request the data from the state to compare to the Medicare data.

Dr. Jernigan agreed and said that DHQP is early in the process and still learning about the best definition of "network" that is most epidemiologically important and helpful. The division can indicate some approaches that are useful now, but with more experience, more can be recommended regarding how to work with data.

This information is critical to controlling AMR. The idea of a regional collaborative network is a good one so that people in the network know each other and have periodic communications to share data and educational programs. When members of a network know each other, they are likely to feel comfortable sharing information about patient movement. The network concept could be part of the expectation for antibiotic stewardship participation that will be a Condition of Participation (CoP). This connection could answer the question of "what's in it for me" for nursing homes.

Although the models use specific interventions, such as active screening and isolation, Dr. Jernigan said that the models are agnostic to the intervention. Any intervention that will decrease transmission at a facility could be used.

Collaboratives share best practices. One institution learns from another. Dr. Jernigan said that on many fronts, collaborative intervention has been very valuable, particularly in situations in which occurrences at a neighbor's facility affect other facilities. Dr. Bell commented that the network modeling exercise showed some unexpected intensity of connection. He asked how this exercise might have led to the rebuilding or redesigning of collaborative relationships.

Dr. Jernigan described a collaborative in Vermont. It is a rural state with few hospitals. Because of the structure of their long-term care, those facilities tend to send their patients to the same hospitals, and vice versa, creating natural clusters. The collaborative organized their intervention into those intervention units. The acute care hospital and its associated long-term

care partners considered themselves the intervention unit. The work considers outcomes at the cluster level.

In Orange County, California, approximately 5000 MRSA isolates have been collected. Their genomics track tightly with patient-sharing, suggesting that the sharing of patients is related to the sharing of strains. There is a contract in place for regional intervention. Part of the modeling phase that will precede the intervention will take the networking links into account. It is voluntary for facilities to participate, but as groups are recruited, they are informed of the links between them and that direct effects and synergy can be detected more clearly depending upon how the groups are designed. Fully-enclosed groups can expect better gains than randomly-picked facilities. If a facility in a group decides not to participate, it is still possible to learn indirect effects. There are ways to be thoughtful about ways to glean information regarding how a group will gain more than an individual acting alone.

Dr. Bell said that there may be a role for state, local, and other health departments to broadcast information about the linkage networks of which facilities might not be aware. Sharing that information will not be threatening, but instead will be useful to end users.

Dr. Cardo said that Dr. Jernigan presented on this topic because many people are unaware of these networks, as they focus on interventions within their facilities. The modeling shows that even a strong program in an individual facility cannot prevent AR. Although the modeling was conducted for CRE, an emerging problem, the results are similar for endemic infections such as MRSA and *C. diff*. Regional collaborations are obviously important, but another aspect of this approach is targeted interventions. At times, an intervention at one facility with a higher burden can help many facilities. Focusing interventions for endemic as well as emerging infections can be more effective. She hoped to learn what might motivate a facility to join a networking initiative. The modeling shows benefit and there are examples of successful collaborations, but even with this evidence, health departments still have challenges in convincing facilities to join the concept. The success depends on having access not only to one or two hospitals, but also to the pathogens in order to guide targeting efforts. Health departments do not need to have all of the expertise. Partners, such as academic centers and professional organizations, can provide expertise. The network might not just be hospitals and healthcare facilities, but different organizations, with each playing a role.

CSTE commented that Tennessee has been very interested in this work. Understanding transmission dynamics was an item of high priority at an EIP meeting years ago. The state hospital discharge database now allows encrypted personal identifiers to be kept at the health department. When one of the Quality Boards from a large healthcare system in Tennessee was presented with the *Vitalsigns*™ report, they were struck by the modeling and are engaging in additional work on CRE and antimicrobial stewardship. They are also meeting with public health and laboratory partners in a bordering state with which they share patients. Many of the population centers in Tennessee are near state borders, so they must think about their neighboring states. Understanding the connections is extremely helpful. CDC's hard work in this area is appreciated.

St. Louis, Missouri receives transfer patients from many states, particularly from Illinois. It is important for state departments to know how to access the data regarding patient connections. St. Louis could be a good setting for a first-step example for state departments to illustrate how the work could be done. The information could also be distributed to hospitals. State and local health department interactions, structures, lines of authority, and activity levels and penetration

into healthcare systems across states vary. Providing the information to infection prevention programs and hospital leadership is likely to be helpful. Regarding messaging of the guidance and rationale, it is important to show the networks without attaching them to a particular organism. The organisms of interest are likely to vary among hospitals. Further, this approach minimizes the possibility of assigning blame to a particular facility within the network.

There is momentum because of the *Vitalsigns*™. It was an important report for public health to begin to understand how to control these problems. The work is so important that it should not wait for a perfect approach. Health departments can build upon existing work and experience.

Dr. Cardo agreed that DHQP will not wait for perfection. They will do what is good enough, and then improve.

Focusing on building capacity at health departments is a good approach. The guidance should come to health departments as opposed to CDC creating a national model. It will be useful for states to determine their cross-border collaborations using that guidance.

Consumer's Union commented that the model is missing patients and their families in the model. They are the group that is most directly affected by these problems, and they can also carry information, informing facilities to which they are transferred about their colonization or infection status. Patients should be informed about these issues, whether they are returning home or going to another facility.

Dr. Jernigan agreed and said that one of the interventions in the model incorporated the broad concept of enhanced communication upon inter-facility transfer. There are many ways to improve that communication, and patients are an important part of it.

Facilities and health departments will be motivated to engage in this work if there is a "how-to" guide on assembling the data. Further, the communication issue is important, especially in reinforcing that this work is a team effort versus blame game. Orange County, California, has benefited from the local APIC chapter in messaging. Communication is important directly to consumers as well as through public health, APIC, SHEA, and other organizations to encourage a regional approach to problems that are broadly contagious.

ACOEM asked whether the models have been informative in clarifying the relative importance of direct institutional transfer versus a scenario in which a patient is transferred home and then readmitted to another institution after some time.

Orange County, California has a population of approximately 3.1 million. Patients who are admitted to a hospital have a 30% chance of being readmitted in the next year. Only half the time do patients return to the same hospital. Rates for nursing homes are higher. LTAC facilities have tighter direct transfers. A great deal of nursing home-to-nursing home sharing occurs, and there is also assisted living flow that is not captured. Data are needed to link these indirect pathways, or consumers need to be empowered to inform. That information should be captured systematically. There are many opportunities to improve communication linkages. Currently, the fastest method is to use state inpatient databases or Medicare data that crosses through nursing homes to understand what is happening in a region.

NACCHO commented that six years after the outbreak in Florida, the LTAC facility is still suffering from the trace back. If these systems and tools are going to be implemented, it is

critical to think about the repercussions. The health department could not help ease the financial burden on the facility. As these tools and capacities are constructed, careful thought should be given to messaging that the effort is not a blame game, but is for the betterment for all. Public health is likely not as prepared to do that as it should be.

Mr. Hageman said that the facility types where this work has begun are appropriate. The next steps might consider incorporating additional types of facilities, such as dialysis centers, with patients who come in and out multiple times per week.

Dr. Bell noted that this work describes risk of transmission and does not address how to shut the transmission of pathogens down. This work illustrates that infection control is not doing as perfect a job as it someday will in terms of preventing transmission at the bedside and within facilities and communities. A great deal of work remains to be done. Their target should be tracking as well as preventing.

HICPAC agreed and noted that in order to coordinate efforts, there must be something to coordinate.

NIH suggested that the ultimate communication solution may be electronic communication. It is a long way away, but they might think about how it might work. Mandatory electronic communication of pathogens when they are detected is one possibility. Often, patients are not detected until they are infected or when a culture is ordered because of suspicion of an infection. This approach provides superficial evidence of a much larger problem. For example, many patients have these organisms in their stool flora and the organisms will not be detected unless they are sought. It is also important to consider the role of the environment for these organisms. Little is known about how the organisms operate in the environment, whether they pass plasmids to one another or across species in the biofilm. This work presents a unique opportunity to make progress on horrid pathogens.

APIC commented on the role of collaboration for success. Healthcare organizations operate in a punitive system, with penalties of lack of reimbursement for HAIs. Somehow, all organizations need to want to participate in a collaborative effort without fear of retribution in order to be successful.

AEH agreed with concerns about financial repercussions when hospitals highlight these problems. Hospitals are asked to show connections between hospitals. Unless testing occurs at a facility, that facility may not necessarily be linked to an outbreak. If an outbreak is detected at a hospital that is tightly linked to an outside facility without that testing capacity, it may not be understood where the organism came from; yet, the linkages will be clear, and the financial penalties will be real.

VA noted that in an outbreak, it is usually possible to get cooperation because of fear. However, it is concerning that when there has been an outbreak, "you've already lost." The question is how to prevent the outbreak. Analyzing the number of patients who are transferred with an organism is also a loss, because most patients do not know if they have CRE because they are not sick from it. The burden of organisms is unknown. When conducting a risk assessment, a facility can determine from which facilities it receives the most transfers. Then, if it is known how much infection the facilities have, then the burden can be estimated. The time to intervene is before an outbreak. Hospitals need guidance regarding what to do with that information before there is a cluster of cases. Should patients who transfer from high-burden facilities all be swabbed, or put into isolation? Performing a nasal swab for MRSA is not usually problematic, but other kinds of swabs are more invasive and require ethical reflection. Knowledge is important, but using it for prevention is the essential next step.

Dr. Jernigan encouraged HICPAC to continue to think about how to overcome the barriers and to implement activities that are doable now as they move toward an ideal.

Sepsis Surveillance Definition Work Update

Anthony Fiore, MD, MPH
Chief, Epidemiology Research and Innovations Branch
Division of Healthcare Quality Promotion
Centers for Disease Control and Prevention

Dr. Fiore updated HICPAC on the sepsis activities in which CDC has been participating. These activities have accelerated because of internal work, as well as work that is external to CDC. Initial care for sepsis has increasingly focused on intervention bundles, which include early-recognition issues such as better fluid and more timely fluid resuscitation, earlier initiation of antibiotics, and lactate levels. On October 1, 2015, CMS implemented a process measure known as "Severe Sepsis and Septic Shock: Management Bundle (NQF measure #0500)," or "SEP-1," in the Hospital Inpatient Quality Reporting Program (HIQR). This measure will focus attention on implementing these bundles.

Moreover, sepsis clinical definitions and interventions are currently in flux. A task force, convened by SCCM and ESCIM, has been working for some time on an evidence-based approach to identifying patients with infections that could lead to sepsis and severe outcomes earlier in order to implement the intervention bundles more quickly. This work is slated for release in 2016 and will allow clinicians to more easily identify cases earlier.

Sepsis is a final common pathway for many common infections. Without early intervention and optimal management, infections can lead to the adverse outcomes associated with sepsis.

Primary prevention focuses on preventing colonization or invasive disease, or prevention of an entry point for the pathogen. The second point is early recognition and diagnosis after the infection has already occurred. The third point, linked to the second, is optimizing the clinical management and treatment of the patient to avoid severe outcomes.

CDC and public health have a major role in the first step of primary prevention. CDC conducts epidemiologic studies and surveillance to inform prevention strategies. CDC uses outbreak response and analysis to inform prevention guidance and education. The agency also provides support for vaccine development and deployment, determining better ways to target vaccines to populations that are prone to developing severe outcomes after infections. Examples of CDC's primary prevention work include:

- Preventing HAIs
- Developing and leading antimicrobial stewardship initiatives
- Supporting vaccine development and programs, which have prevented hundreds of thousands of infections that could have led to sepsis
- Peri- or post-exposure prophylaxis for invasive pathogens, such as Group B *Streptococcus* in young infants
- Preventing or reducing situations that put people at risk for infection: this work includes the entire agency, even in the non-infectious realm, in areas such as better diabetes identification and management

CDC engages in a great deal of sepsis-related communication. A variety of patient materials have been developed and released, particularly during September, which is Sepsis Awareness Month. These materials, such as fact sheets, provide simple information for consumers, patients, and clinicians to help them think about sepsis early. They describe the impact of sepsis and identify ways to intervene for sepsis early in the infection.

CDC collaborated with clinical partners and patient advocacy organizations during Sepsis Awareness Month in 2015. Other activities included a video from CDC Director Dr. Tom Frieden, a blog series on CDC's Safe Healthcare Blog written by people who had been personally affected by sepsis, and a Twitter chat. There were over 70,000 visits to the sepsis website during September.

A number of challenges are associated with identifying sepsis and tracking its burden. Sepsis is a difficult syndromic definition that is based on a clinician initially suspecting infection. There is no gold standard diagnostic test. Cultures are often negative among patients who meet sepsis criteria, and biomarkers are not adequate. Many patients who develop sepsis initially become ill in the community and have an initial encounter in an outpatient setting or the emergency department. There are concerns that the 2001 sepsis definition does not capture some cases and is not consistently applied by clinicians. Further, the Systemic Inflammatory Response Syndrome (SIRS) criteria are not specific enough and are not adequate to distinguish severe sepsis. The optimal bundled interventions are not defined. Death certificate data are problematic, given that this is dependent upon a clinician assigning sepsis as the underlying or contributing cause of death. Recent estimates of sepsis have relied on administrative claims data, but a variety of analyses suggest that there is increasing incidence of sepsis accompanied by decreasing mortality. This finding may imply that care is improving, but these changes are accompanied by no change or decreases in the incidence of typical underlying infections. Therefore, the change could be a result of coding becoming more effective at identifying sepsis, possibly driven by improved reimbursement for sepsis so that patients are now coded with sepsis who might previously have been coded with the underlying infection.

A recent study used national data between 2003 and 2011 to demonstrate that sepsis has more than doubled, while the underlying major drivers of sepsis, such as pneumonia, intraabdominal infections, and urinary tract infections (UTIs), are essentially flat of have decreased. Using EHRs and chart reviews, investigators have developed convincing evidence that the increase in sepsis is the result of clinicians and coders being better at recognizing and coding sepsis.

The field has recognized that several sepsis definitions are needed to address various key issues for clinicians. Early detection and implementation of interventions is important, so the definition needs to be sensitive and include elements that are easily captured during an initial clinical encounter. Research studies need a specific sepsis definition. For national surveillance, a definition is needed that is specific and consistent over time. To reduce the burden on reporting if there were national surveillance for sepsis, elements should be easily captured using EHRs. CDC can take the lead in this area.

CDC has been working with the Harvard Prevention Epicenter and partners to develop and test a surveillance definition based on electronic clinical data. This work is an extension of Harvard's previous work. Electronic surveillance definitions will be tested across multiple healthcare systems and hundreds of hospitals to determine how well they can consistently capture patients that have sepsis. The goals for Year 1 are to: 1) develop estimates of national incidence and mortality burden for sepsis and septic shock based on the EHR data; and 2) characterize trends in sepsis incidence and mortality.

CDC will continue work with critical care experts to establish groundwork for understanding the relationship between clinical definitions that are meant to capture sepsis at an early state and the surveillance definitions that will be more specific and stable over time.

CDC is also planning additional activities, including the following:

- Conduct studies that will better define risk factors, microbiologic causes, preventable fraction of sepsis cases to target prevention efforts
- Assess sepsis definition candidates from the work of Harvard and partners that uses electronic clinical data to determine how they could be adapted for national surveillance
- Continue engagement with critical care experts, clinicians, and the public to increase awareness of sepsis prevention and support and promote effective early intervention measures
- Work with partners to identify opportunities to improve and assess early intervention impact, including antibiotic use, which may change based on early identification
- Emphasize primary prevention programs, such as adult vaccination programs and work on HAIs, that prevent infections that cause sepsis

HICPAC and its liaison representatives can support these efforts by increasing awareness of interventions within their organizations. When DHQP arrives at a surveillance definition, HICPAC can vet that definition.

Discussion Points

SIS asked about the emphasis that the surveillance definitions will place on actual documentation of the presence of bacteria or viruses. Many patients who are treated for sepsis have negative cultures and high antimicrobial usage. If the definitions are based on positive cultures, then the results will be different from the results of the current definition.

Dr. Fiore said that with an EHR definition, it will be possible to capture positive cultures. CDC is also interested in patients who enter into the sepsis treatment pathway. Many of those patients without positive cultures could be sepsis patients and could benefit from antibiotics and aggressive fluid resuscitation.

HICPAC noted that this point relates to research that still must happen regarding culture-negative patients who clearly have sepsis, and whether advanced molecular detection (AMD) and other approaches could provide more understanding. These approaches could detect pathogens that caused the initial illness if the patients are culture-negative because they have received antibiotics.

When new measurement systems are implemented, emergency medicine, hospital medicine, and ambulatory medicine should be involved. HICPAC cautioned DHQP to ensure that the modeling and data capture for the measures accounts for what happens when critical values are missing. When critical pieces of information are missing, there can be gaps in the electronic measures and in the patient's prognosis and severity of illness. In some cases, missing information can be a surrogate for the type of care that a patient is receiving.

Dr. Fiore pointed out that the CMS process measures will capture those points, as they assess which patients are missing values or received antibiotics and fluid resuscitation later.

SCCM said that Dr. Fiore elucidated the complexity of the issue clearly. With molecular methods, patients can be detected when they have an infection but are culture-negative. It is important to understand that the downside of not providing antimicrobials to those patients may be high from a mortality standpoint.

Ensuring Training and Competency of Healthcare Personnel in Infection Control

Michael Bell, MD
Deputy Director
Division of Healthcare Quality Promotion
National Center for Emerging and Zoonotic Infectious Diseases
Centers for Disease Control and Prevention

Dr. Bell described DHQP's work in recognition of daunting realities in medicine. It is clear that infection control practice and understanding are not hand-in-hand in a broad range of facilities in the US. In hospital assessments of facilities of a range of sizes, there is a "ceremonial" approach to infection control and a belief system associated with personal protective equipment (PPE). In reality, a healthcare worker's actions need to be safe and correct in order to protect himself and patients.

This issue is related to a reduction in the amount of basic microbiologic training that is received as curricula in this area in nursing and medical schools have eroded. At the same time, there is an absence of focus on risk assessment. Risk assessment, whether of a device or another aspect of healthcare, is rooted in understanding potential sources of risk and following up on them.

Training in infection prevention was delivered at CDC in the past. That system ended in the 1990s because it is expensive, but it may be worth re-linking given the balance of cost and impact. DHQP is in the process of rethinking and reconsidering what type of training is needed in infection control and in improving the quality of healthcare. The training will not duplicate existing tools. The element of sustainability will be based on understanding. This training should include more than the usual groups. The focus on clinical staff alone is insufficient. There is increasing need for materials management and environmental services to be part of the group that is trained in risk assessment and infection prevention.

DHQP is establishing a new group to serve different needs, including training. It is important not to lose momentum in healthcare facility assessments. They are a valuable way to interact with local and state health departments to have a more robust connection with healthcare delivery. These connections can incorporate TAP assessments and facility review consultation in ways that can materially improve practices. Most facilities do not have the necessary expertise and resources that need to be brought to bear in a broad way, especially in nursing homes and other facilities where care is provided, but not enough measures are in place to maintain safety and infection control. The new group will include Kathy Dunn from PHAC to lead a team to focus on the training aspects of infection control. She has experience in the Canadian government as well as an ICU nurse and instructor.

The group will incorporate a guidelines group. DHQP is evolving its approach to guidelines, and the combination of training, guidelines, and consultation is a natural fit. The next steps in guidelines will not adhere to the former approach of taking years to write, in effect, a book. This timeline is not doable given the pace at which evidence moves. Rather, the guidelines will be

electronic and accessed and searched as a single body of information. The recommendations for the core elements that do not have evidence, do not need evidence, and will never change, will be codified separately from the recommendations that are expected to be updated. The new group will determine how to do that updating.

This work will include determining how to assess evidence more efficiently. The GRADE approach is not sufficient, and they are in the process of redefining the range of evidence to consider beyond RCTs to include retrospective studies, outbreak studies, and other examples of evidence that should be considered. The group will consider the range of available evidence and understand how the different types of evidence should be graded and weighted against each other.

Related to this effort is work in innovations in information technology (IT). DHQP is discussing tools such as full text review, natural language analysis, and other tools that can be part of a learning system. If this system can be applied to initial manuscript pulls for evidence reviews, then the process of answering specific questions based on evidence will speed up. The system could even incorporate some of the ranking processes that are conducted by hand. Further, data systems update periodically, so it might be possible to conduct a fresh search on relevant questions on a weekly basis. If so, at a certain threshold of either quantity or significance of evidence a list of questions can be brought forward for consideration. This process could be valuable not only in helping to answer questions, but in deciding which questions to answer first.

This process is different from past approaches, but it is likely to be more useful. The comfort level with using electronic information is increasing. There is an opportunity, as with NHSN data, for smartphone technology to be more useful for guidelines and recommendations.

Working groups of HICPAC require two HICPAC members to lead them, but they can include staff from DHQP, other federal colleagues, and outside experts. Working groups cannot directly make recommendations. Recommendations from HICPAC have to be presented during a public meeting. These meetings, whether held in person or via teleconference, are advertised in the *Federal Register* for three months. HICPAC members can participate on more than one working group, and the results of their deliberations are reported to the HICPAC co-chairs.

DHQP will provide a calendar of working group teleconferences and schedules. This approach will allow for segmental updates of guidelines with an eye toward eventual rolling updates prioritized by need and importance for patient safety. An interactive, transparent product is the goal.

Training should initially focus on risk management. This step is largely lacking in all training. CDC has contracts with many partner organizations, from ANA, APIC, and SHEA, to professional societies representing environmental services and materials management. Connections are strong with HRET and its membership groups. Unions also have significant reach to important groups. CDC will provide content to these groups and work with them to develop additional content, as well as endeavor to deliver the material effectively.

Risk assessment efforts will begin in clinical settings, as the immediate patient care environment is a reasonable place to start. It will extend to other elements of the environment. There could be different modules for different elements of care, such as waste handling or laboratory biosafety, in concert with other partners. This skill set is needed in all areas. The goal is to have

a training app available for download within one calendar year. This tool would be accessible to a range of people on their own time and could have widespread impact.

Discussion Points

HICPAC expressed support for the changes to the guideline editing and production process.

HICPAC members appreciate updates on the status of guidelines, as they are approached with questions by their colleagues.

Standardized training will be beneficial. Microbiology is extremely important. In many hospitals, consultants are cutting laboratory resources, including microbiology resources, which limits capacity and affects the timeliness and accuracy of susceptibility reports and has implications for antibiotic stewardship and resistance. The emphasis on microbiology in training and stewardship is appreciated.

Dr. Bell emphasized that all providers should receive training, not just infection control professionals or hospital epidemiologists. Determining how to measure competency in infection control is a challenge. HICPAC's input may be requested in the future regarding criteria that are essential components of demonstrating competency. Some of this work has been done by other partner associations. HICPAC can provide a broad perspective of how these criteria could work and link to health department oversight, licensure, and other issues. Regarding microbiology, having this expertise onsite is ideal for risk assessment. Discussions are ongoing regarding gram stains and other tools that are useful in certain clinical settings. As the ability to study organisms moves away from clinicians, they are less aware of them. Understanding of germ theory should be increased.

Summary and Work Plan

Dr. Diekema raised items that HICPAC is interested in moving forward:

- ❑ Improving the initial risk assessment of medical devices, their infection control, unintended consequences, the ability to ensure that manufacturers demonstrate efficient and effective methods of cleaning, and a set of minimum standards for the evaluation of these devices prior to marketing.
- ❑ Providing a structure or framework for those who promulgate treatment guidelines to help them incorporate stewardship principles into the guidelines.

Dr. Bell hoped that by the end of November 2015, a list could be generated of elements for HICPAC to consider regarding medical devices. The co-chairs can deliver the list to HICPAC, which can share comments and additional considerations. These elements can serve as interim criteria and may be useful for other partners to use as a starting point.

Regarding stewardship and treatment guidelines, Dr. Bell said that having actionable recommendations for including phrases that meaningfully balance the dynamic between encouraging too much antibiotic use and doing the right thing for the patient in terms of the treatment and prevention of sepsis will provide a framework for myriad partner societies.

Discussion Points

Dr. Cardo suggested that the framework could begin with the principles provided by Dr. Hicks.

HICPAC discussed an issue that has arisen. The Office for Human Research Protections (OHRP) has released a common rule change for Institutional Review Boards (IRBs) to the *Federal Register* for feedback. This proposed change is relevant to HICPAC members, liaisons, and ex officio members.

The draft guidance attempts to clarify what constitutes research oversight, QI, and public health authority. The change is intended to be helpful, but it is alarming where the line was drawn. As stated, the rule indicates that QI is restricted to only elements that check that a facility is appropriately implementing something that is already the gold standard. For instance, if a facility wishes to reduce *C. diff* rates, it could implement an activity that checks hand-washing, but it cannot implement an activity with the goal of reducing the rate of *C. diff*. Any activity examining the effective measure of the outcome itself falls under IRB jurisdiction.

For example, if sepsis is an outcome, the only permitted activity would be to check that a bundle is happening once the bundle is known. An activity cannot engage in innovative activities that are operational at a facility that could impact the outcome. These activities would be considered new science that falls under IRB regulation.

It is important for OHRP to hear from consumer groups and societies to protect the operational work that goes on for the greater good in response to the HHS action plan and to CMS mandates. The proposed rule change defines public health activities, which has been a subject of deep ethical debate for some time. Oversight and ethics are needed, but the proposed rule has drawn the line in a concerning manner. OHRP also defines that certain type of activities, such as outbreak response and emergency response, are public health domain. It states that determining risk factors for diseases is considered under IRB oversight. With this approach, a state health department cannot use NHSN or other data to define risk factors related to a disease in an area.

It is important for OHRP to hear from those in QI and public health to understand what has been considered operational and necessary to protect the well-being of patients.

OHRP received input from stakeholders to derive a reasonable determination of QI versus research. Some institutions have an oversight process for determining QI versus research projects. The proposed document is concerning, as it does not appreciate the basic tenets of QI: "Plan, Do, Study, Act." This approach allows for local interventions and evaluating process as well as outcome measures. The proposed rule cites a document about social science research as rationale for making the changes. All QI is local, and it is concerning for this document to be released without input from QI professionals. It is a threat to patients if institutions are not able to improve their processes and outcomes constantly.

Many facilities do not have IRBs.

Dr. Bell appreciated the information about the proposed rule. DHQP is determining whether HICPAC can make a formal statement about this rule as a committee. As individuals and independent scholars, they are free to make comments.

CSTE said that because of the tight timeline, it will be important to get input from different groups to ensure that the response is well-rounded from the public health and QI perspectives.

Public Comment

Dr. Diekema opened the floor for public comment at 11:23 am.

Robert Jones
Managing Partner
Energy & Environmental Enterprises, LLC

Mr. Jones addressed HICPAC representing Goldshield, a new water-based antimicrobial with a unique residual efficacy, which was referred to CDC by the US Environmental Protection Agency (EPA). EPA has no existing protocol to test the long-term residual efficacy of antimicrobials. Goldshield currently has EPA and FDA approvals under the existing protocols and is just beginning to distribute these products in the US.

In the November edition of the *American Journal of Infection Control* (*AJIC*), there is an article discussing a nine-month clinical trial of this product at Oakwood Hospital in Michigan. One application every 30 days, in concert with once-a-day cleaning, reduced the bioburden 3 to 4 logs on the surfaces tested. An ideal application might also include privacy curtains or healthcare uniforms in hospitals and bed linens in extended-care facilities. The cost to deploy this material on surfaces is comparable to current practices. The product is beginning to be used with success in the United Kingdom National Healthcare System.

As healthcare leaders, Goldshield wishes to make HICPAC aware that there is a non-leaching, non-migrating technology with studies showing residual protection on surfaces, textiles, and equipment. It has not demonstrated any substantial evidence of genetic adaptation. It is also approved as a water-based hand sanitizer.

Even after a nine-month clinical trial, amassing over 60,000 cultures and 38 other evidence-based studies, healthcare facilities would benefit greatly from HICPAC's insight to help provide the guidelines and test protocols so that they can optimize this tool as part of a comprehensive program.

Dr. Diekema thanked Mr. Jones and noted the relevance of his comment to HICPAC's discussions regarding environmental contributions to infection prevention.

Adjourn

With no additional comments or questions, the HICPAC meeting adjourned at 11:25 am. The next meeting is scheduled for March 31-April 1, 2016.

Certification

I hereby certify that, to the best of my knowledge and ability, the foregoing minutes of the November 5-6, 2015 meeting of the Healthcare Infection Control Practices Advisory Committee, CDC are accurate and complete.

_____
Date

_____
Daniel Diekema, MD or Deborah Yokoe, MD, MPH
Co-Chair, Healthcare Infection Control Practices
Advisory Committee, CDC